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ABSTRACT

Hearings on the use of computer technology in the health care field are presented to provide information needed by Congress and the Food and Drug Administration to make future policies. Medical computing systems can make interpretations of data on the patient's health and can generate diagnostic recommendations to the physician. Included are testimony/articles on: a medical expert system involving diagnosis in internal medicine, called both INTERNIST-I and CADUCEUS; a computing system called HELP (Health Evaluation through Logical Processing) that rapidly provides information to support decision-making by medical personnel; marketing clinical expert systems (artificial intelligence software); the impact on costs of a computer that documents respiratory care; the security employed with clinical expert systems so that unauthorized persons cannot obtain patients' records; and the question of whether medical software should be exempt from liability or federal regulation, and specifically whether medical computing systems are subject to regulation under the Food, Drug, and Cosmetic Act. (SW)

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INFORMATION TECHNOLOGIES IN THE HEALTH CARE SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

APRIL 21, 1986

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*Ranking Republican Member.
**Serving on Committee on the Budget for 99th Congress.

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INFORMATION TECHNOLOGIES IN THE HEALTH CARE SYSTEM

MONDAY, APRIL 21, 1986

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2325, Rayburn House Office Building, Hon. Harold L. Volkmer (chairman of the subcommittee) presiding.

Mr. VOLKMER. Good morning.

The subcommittee will come to order.

The Subcommittee on Investigations and Oversight is beginning a study of the issues that Congress can expect to face as the use of computer technology becomes widespread in the health care system.

Medical research is providing doctors and hospitals with important new knowledge and valuable new tools every day. Attempting to keep pace with these new developments will be an increasingly difficult problem for physicians. Technology in the form of specialized computer systems may offer an avenue for doctors to use in managing these competing demands on their time.

This committee has addressed the issues raised by medical information systems in 1978 and 1981, so we are building on a solid foundation. Our renewed interest in this area is dictated by the fact that the Food and Drug Administration has been wrestling for over 5 years with the development of a policy statement that will guide regulation of medical software under the authority of the Medical Device Instruments Act of 1976. I am beginning to understand the frustration this has caused.

Despite the fact that this hearing was delayed 1 month, FDA was unable to provide a statement for the record until the last minute before today's hearing. It will be interesting to see if our witnesses consider that it represent—that represents progress.

The computer's unmatched ability to store and manipulate information has been welcomed by hospitals trying to meet the administrative and regulatory burdens involved in quality patient care. It is perhaps natural that doctors are now beginning to see the possibilities inherent in the use of computers for the storage of medical records.

I am concerned, however, that storing sensitive and personal information on a computer system may cause new problems in protecting a person's constitutional right to privacy. There are some

very difficult considerations involved, especially if remote access to the computer system is permitted.

This hearing is intended to continue the debate on these issues and to develop other topics for discussion in this area. I intend to see that this subcommittee contributes to the success of these technologies and welcome the assistance of the community in doing so.

At this time I'd like to recognize the subcommittee's ranking Republican member, Congressman Ron Packard, for any remarks he may have.

Mr. PACKARD. Thank you, Mr. Chairman.

Computers have become commonplace in our lives and have been used in the medical field for some time. As computers have become more sophisticated, the nature of their use is changing from merely storing information and performing basic calculations to directly interacting with patients using artificial intelligence techniques.

It is clear to see that computers have the potential of revolutionizing medical practices and general health care as we know it today. As with any other new technology, it is necessary to evaluate whether or not it will perform as intended and not cause harm as a result.

Today's hearing is intended to provide this subcommittee and the Food and Drug Administration with information needed to make informed judgments about future policies that will affect the use of expert systems in the health care industry.

Mr. Chairman, I'm very pleased that you've called these hearings, and I appreciate the appearance of these very respected leaders in this field and am looking forward to their testimony.

Thank you very much.

Mr. VOLKMER. Thank you.

To begin the hearing, I would like to introduce our first panel. Dr. Jack Myers, professor emeritus at the University of Pittsburgh, has been invited to describe the work in medical expert systems he has pursued for more than a decade. Dr. Myers is one of the developers of Caduceus, a prototype expert system involving internal medicine.

Dr. Reed Gardner is part of the team that has built the HELP—that's Health Evaluation through Logical Processing—system first installed at the Latter-Day Saints Hospital in Salt Lake City now being used at a number of other facilities around the country. We have asked Dr. Gardner to explain for us the expanded uses of medical records incorporated in that system.

Mr. William Baker is a former special assistant for biomedical engineering from the National Institutes of Health, and in that position was responsible for allocating Federal research funds to projects that sought health care applications for artificial intelligence techniques. He has since left the Federal Government and established a private company for the purpose of marketing systems like Caduceus. We are very interested in the success he has enjoyed and the problems he has encountered.

Gentlemen, we appreciate very much having you here today. Your written statements, which I have reviewed, will be made a part of the record in their entirety. You may either summarize those written statements now in your oral testimony, or you can read them in full—however you so desire.

Dr. Myers, would you please begin.

STATEMENTS OF JACK MYERS, PH.D., UNIVERSITY OF PITTSBURGH, PITTSBURGH, PA; REED GARDNER, PH.D., LATTER-DAY SAINTS HOSPITAL, SALT LAKE CITY, UT; AND WILLIAM BAKER, KNOWLEDGE RESEARCH ASSOCIATES, POTOMAC, MD

Dr. MYERS. Thank you, Mr. Chairman.

I would like to hit some high points of what I wrote rather than read it.

I suppose some might wonder what an old codger of 72 is doing in a computer field that is largely reserved for young people. I first want to explain how I got into this situation then.

I've had almost 50 years now of academic, clinical medical experience, and it became very obvious in the 1960's and extending into the 1970's and even today that in my field of internal medicine—and this can apply to any other broad field—that the amount of medical information is far beyond what any human being can contain.

Now we've got about 80 percent of internal medicine programmed already, so I can make some quite accurate projections as to how many items of information in this broad field there are today; it's over 400,000. The memory of persons like ourselves when we're trying to solve a problem is limited to about 100,000 items of information, which means that when the expert physician encounters an unusual problem that he, from his own memory, can only bring about a quarter of the information that may be needed to solve that problem, and that, I think you can see, presents a real issue for the medical profession.

The second point I would want to make is that when you and I try to solve a complicated problem, that at any one point in time we can only think of seven potential answers. Now if you go to the extreme, it would be about 10.

What we have to do then in solving a problem is look at our considerations and say, well, you know, two of those don't have good support; let's forget them and bring in two more.

We know from our computer work that in complex problems, again, there may be dozens of tenable hypotheses, and obviously the solver of the problem just doesn't get to the right consideration and therefore doesn't come to the right answer.

I think those are two very telling reasons then why we have to have computers in medicine to aid in diagnosis in other* branches of practice.

So we set out in the early 1970's to build this broad program. I have to say it's still in the stage of research and development. We have almost 200 diseases to program yet. The medical knowledge base, though, as I said, includes about 80 percent of that over 400,000 pieces of information.

I have to be a little careful about that figure, though, because, you know, every week new information comes along, new diseases are described, so nothing is static in this particular field.

The knowledge base, which is an essential part of any expert program, is being used now in medical education in probably a couple of dozen of our medical schools, and recently I had the honor to

*Dr. Meyers asked that "other" be changed to "various" See p. 279.

chair a committee that brought out this report, Medical Education in the Information Age [1]—I'm sure you haven't had a chance to see it; it only came out last week from the American Association of Medical Colleges [AAMC]—and it emphasizes some of the things I'm talking about in knowledge bases in undergraduate medical education as well as in medical practice.

The other part of any expert system is what is called the inference engine written by the computer scientist to manipulate—analyze the information which is put in, and, again, I think all of us change that inference engine from our experience, and so again nothing is static there.

Now I want—the other point I want to emphasize is our view of how these systems can be used. The expert knowledge base, of course, can be used just to simply retrieve information. It's an electronic textbook, if you will, and nothing more.

The diagnostic problem which then includes the inference engine as well as the expert knowledge base we have never viewed to be a free-standing program. This is a program in which the physician, when he encounters a difficult problem—and depending on his practice, that won't be more than 5 to 10 percent of his patients, in internal medicine I'm speaking—when he encounters a difficult or complex problem, will enter the patient's information, the computer will analyze the data and will be an adviser to him. He can either throw the data away, throw the recommendations away, or accept them, according to his best medical judgment, and I think that's an important philosophic point about such programs as ours. They're not intended to in any sense replace the physician or to be used directly by the patient. That would be very treacherous. They are consultant to the physician, and I think you can see that that point of view—and others agree—bears directly on whether these programs would have medical liability or not. They're sort of like the physician going to the library, looking up the problems, getting data, saying, "Well, this helps me in this way in solving Mr. Smith's diagnostic, and eventually therapeutic, problem."

Well, Mr. Chairman, I'll stop there and entertain any questions now or later that you may want.

[The prepared statement of Dr. Myers follows:]

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[1] "Medical Education in the Information Age: Proceedings of the Symposium on Medical Information" (Washington, American Association of Medical Colleges, 1986).

Written Statement of J. D. Myers, M.D. for the Subcommittee on Investigations and Oversight of the Committee on Science and Technology - March 10, 1986

During my tenure as Professor and Chairman of the Department of Medicine at the University of Pittsburgh School of Medicine from 1955 to 1970 it became progressively apparent that two problems hindered correct medical diagnosis and therefore correct subsequent treatment of patients.

The first of these problems was caused by the large information expansion in medicine, and in internal medicine in particular, subsequent to the large increase in basic and clinical medical research which began in the early 1950s. Thusly, the knowledge base in internal medicine by the 1980s has grown to exceed the capacity of human memory by several fold. The clinician, therefore, needs some mechanism for reliable storage and easily available retrieval of clinical information of all sorts.

The second problem has to do with human problem solving. It has been shown by our colleagues at Carnegie Mellon University of Pittsburgh that the expert human in solving a complex or difficult problem can deal with only 7 ± 2 (standard deviation) hypotheses (potentially correct solutions) at any point in time. In order to exceed about 10 tenable hypotheses, the human must reject several as not having adequate supporting evidence and thusly work up the list, e.g. to hypotheses number 11 and 12. We have evidence that in the solution of a difficult or complex diagnostic problem in internal medicine that there may be dozens of reasonable and tenable hypotheses.

As a resultof these two problems, the physician in dealing with difficult diagnostic situations (probably not over 10 percent of all problems in internal medicine, depending on the nature of the internist's practice) is hampered by a limitation in memory and by a second limitation in hypothesis formulation ("Why didn't I think of that?").

The author recognized these two problems in qualitative terms when he left the chair of medicine in 1970 and was appointed University Professor, a position which provides almost complete liberty for research. It was realized that the computer provided the proper technology of information storage and retrieval and, after consultation with computer scientists, that the computer might accomplish information analysis and manipulation so as to lead to advice regarding correct diagnostic conclusions. Thus began our work on INTERNIST-I and CADUCEUS (names for different stages of the program). Dr. Harry E. Pople has been the senior computer scientist on the program and the author has been the senior clinician but many junior persons have aided in the program, particularly Dr. Randolph A. Miller.

Expert systems which utilize the techniques of artificial intelligence are built to simulate the human process of problem solution. Such a program consists of two components: (1) an expert knowledge base and (2) the computer operating system (the "inference engine"). A knowledge base is more than a data base; a knowledge base is more than a list of items of information and includes information about the inter-relationships of such items, e.g. one must know that A is present before considering B, or that C and D are incompatible, etc., etc.

Written Statement of J. D. Myers, M.D. (continued - page 2)

Our program, after about 15 years of work, now consists of the profiles of approximately 575 diseases in internal medicine and the program has knowledge of over 4,000 individual manifestations of disease. In addition, it contains thousands of inter-relationships among diseases and tens of thousands of inter-relationship among the manifestations. The profile of any one of these diseases or the list of diseases in which any manifestation occurs can be obtained from the computer in less than one minute. Also readily available are lists of the inter-connections among diseases (LINKS). Semiquantitative values are given for each individual item. Thus, the knowledge base serves as an electronic textbook of medicine, independent of the diagnostic consultant program. It must be emphasized that, in order that an expert system be effective, it must have an expert knowledge base as its foundation. No matter how good is the inference engine, it cannot operate effectively without an expert knowledge base.

In the operation of INTERNIST-I:CADUCEUS, the physician enters into the computer the uninterpreted clinical findings on the problem patient - the medical history, physical findings, and any laboratory data available (clinical laboratory data, radiological findings, biopsies, etc.). He also enters what he considers to be pertinent negative findings. The computer evokes every disease in which each positive finding occurs. Thus nothing is overlooked. Naturally positive findings cluster under the most plausible diagnoses. As a result, each evoked diagnosis is assigned a mathematical value. This is not simply a probabilistic value. The evoked diagnoses are then partitioned so that various heart diseases are competitors with other heart diseases, etc. It would be illogical to try to differentiate a heart disease from a neurological disease; the patient might have both. If the supportive information is adequate, the computer advises the physician that a certain diagnosis or set of diagnoses are well supported. If not, the computer program invokes one of several types of further analysis and by an interrogative mode indicates to the physician what further information would be valuable in solving the problem at hand. If no diagnosis is strongly supported, the system indicates to the physician the differential diagnosis of the problem in order of supporting evidence.

INTERNIST-I:CADUCEUS has been tested on over a thousand difficult diagnostic problems and it performs as well as the skilled clinician but not as well as the very best expert. We hope with further refinement to reach the latter goal, however. The greatest current limitation of the program is that only about 575 diseases, out of a total of about 750 in internal medicine are profiled. A limitation of computer programs is that they can never recognize a disease which they have never heard about. We are working continuously to fill this gap.

As a result of the above mentioned limitations, the diagnostic system has almost exclusively been utilized in our own "shop" where we have control of the situation. The only exceptions are a few cases where we have had personal interaction with the clinician and can express the current limitations of the program. The knowledge base, without the diagnostic consultant program, has been provided to dozens of academic medical centers both in the U.S. and abroad. The knowledge base per se is useful in medical education at all levels as an "electronic textbook."

Before the system can be released for general use by the medical community, it is evident that the currently unprofiled diseases must be included and, furthermore, the system must undergo a controlled clinical trial in order to verify its reliability. This is several years into the future.

Written Statement of J. D. Myers, M.D. (continued - page 3)

INTERNIST-I:CADUCEUS is not intended to be a free-standing program. It is intended to give diagnostic advice to the clinician, advice which he can either accept or reject depending on his clinical judgment. Experience to date, however, indicates that the system will be effective in overcoming the previously expressed limitations in medical diagnosis -- the limitations in human memory in the face of a huge information explosion, which can only become larger, and the limitation in human hypothesis formulation.

A knotty and unsolved issue at the present is the liability of such computer programs as ours. It is emphasized that such programs are not intended to be free-standing. Instead, they are a source of information and of diagnostic advice to the clinician which he has the option of accepting or rejecting. It is our considered opinion that, if explicit liability is placed on such advisory programs as ours, these programs will remain in the academic realm for the foreseeable future.

Biographical Sketch of Jack D. Myers, M.D.

Born May 24, 1913 - New Brighton, Pa.
Raised in Arizona 1919-1938
A.B. Stanford University, 1933
M.D. Stanford University, 1937

Graduate education in internal medicine:
Stanford and Harvard Universities 1937-42

Capt. to Lt. Col. - U.S. Army - 1942-46

Medical faculties of Emory University and Duke University - 1946-55

Professor and Chairman, Department of Medicine, University of Pittsburgh - 1955-70

University Professor (Medicine), University of Pittsburgh - 1970-85

University Professor Emeritus, University of Pittsburgh - 1985-

Main subject of clinical research, 1946-1955,liver blood flow and metabolism.

Engaged in research on computer applications to diagnostic systems in medicine, utilizing techniques of artificial intelligence, 1972 to date.

Past President - American College of Physicians
Past Chairman - American Board of Internal Medicine
Residency Review Committee in Internal Medicine
Coordinating Council on Medical Education
Accreditation Committee on Graduate Medical Education

SPECIAL ARTICLE

INTERNIST-I, AN EXPERIMENTAL COMPUTER-BASED DIAGNOSTIC CONSULTANT FOR GENERAL INTERNAL MEDICINE

Randolph A. Miller, M.D., Harry E. Pople, Jr., Ph.D., and Jack D. Myers, M.D.

Abstract INTERNIST-I is an experimental computer program capable of making multiple and complex diagnoses in internal medicine. It differs from most other programs for computer-assisted diagnosis in the generality of its approach and the size and diversity of its knowledge base. To document the strengths and weaknesses of the program we performed a systematic evaluation of the capabilities of INTERNIST-I. Its performance on a series of 19 clinicopathological exercises (Case Records of the Massachusetts General Hospital) published in the *Journal* appeared qualitatively similar to that of the hospital clinicians but inferior to that of the case discussants. The evaluation demonstrated that the present form of the program is not sufficiently reliable for clinical applications. Specific deficiencies that must be overcome include the program's inability to reason anatomically or temporally, its inability to construct differential diagnoses spanning multiple problem areas, its occasional attribution of findings to improper causes, and its inability to explain its "thinking." (N Engl J Med. 1982; 307:468-76.)

INTERNIST-I, an experimental program for computer-assisted diagnosis in general internal medicine, differs considerably in scope from other medical diagnostic computer programs. In the past, techniques including mathematical modeling, use of Bayesian statistics, pattern recognition, and other approaches[1-3] have been shown to be useful in circumscribed areas, such as the differential diagnosis of abdominal pain[4] and the diagnosis and treatment of meningitis.[5] However, no program developed for use in a limited domain has been successfully adapted for more generalized use. From its inception, INTERNIST-I has addressed the problem of diagnosis within the broad context of general internal medicine.[6-8] Given a patient's initial history, results of a physical examination, or laboratory findings, INTERNIST-I was designed to aid the physician with the patient's workup in order to make multiple and complex diagnoses. The capabilities of the system derive from its extensive knowledge base and from heuristic computer programs that can construct and resolve differential diagnoses.

From the Decision Systems Laboratory, the Department of Medicine, School of Medicine, and the Graduate School of Business, University of Pittsburgh. Address reprint requests to Dr. Miller at the University of Pittsburgh, Decision Systems Laboratory, 1360 Scaife Hall, Pittsburgh, PA 15261.

The INTERNIST-I/CADUCEUS project is supported by grants from the Division of Research Resources (R24 RR 01101) and the National Library of Medicine (R01 LM 01710 and R23 LM03589), National Institutes of Health. The SUMEX Computing Project is supported by a grant (RR 00785) from the Biotechnology Resources Program, National Institutes of Health.

The INTERNIST-I program represents an example of applied symbolic reasoning ("artificial intelligence"). A variety of such techniques have been developed by computer scientists in an attempt to model the thought processes and problem-solving methods employed by human beings.[9,10] An important aspect of the INTERNIST-I approach to computer-assisted diagnosis is that the program attempts to form an appropriate differential diagnosis in individual "problem areas." A problem area is defined as a selected group of observed findings, the differential diagnosis of which forms what is assumed to be a mutually exclusive, closed (i.e., exhaustive) set of diagnoses. Physicians routinely construct such closed differential diagnoses on the basis of causal considerations (e.g., bacterial pneumonias) or pathoanatomic considerations (e.g., causes of obstructive jaundice). By constructing specific differential diagnoses to address identified problem areas, a physician or computer program can narrow the set of possible diagnoses from all known diseases to well-defined collections of competing diagnoses in a small number of categories. Heuristic principles, such as diagnosis by exclusion, can then be employed to resolve each differential diagnosis. The use of such strategies in INTERNIST-I represents an attempt to model the behavior of physicians.

Reported below is the first systematic evaluation of INTERNIST-I. The purpose of the study was to illustrate the strengths and weaknesses of the program and

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307:468-476 (August 19), 1982

to provide a rough estimate of its clinical acumen. The trial was conducted with clinicopathological conferences (CPCs) that had been published in the *Journal* but had not previously been analyzed by the system. The CPCs fulfill the criteria of being diagnostically challenging cases and of containing sufficiently detailed information to allow computer analysis. The evaluation was not intended to validate INTERNIST-I for clinical use. CPCs should not be used for such a purpose, and as the trial demonstrated, the program does not yet possess sufficient reliability for clinical application. Nevertheless, INTERNIST-I performed remarkably well, considering the simple, ad hoc nature of its algorithms.

The Internist-I Data Base

A medical knowledge base must meet the needs of any associated diagnostic programs. In particular, the INTERNIST-I knowledge base was designed to permit the consultant program to construct and resolve differential diagnoses. The knowledge base incorporates individual disease profiles, which list findings that can occur in patients with each illness. By inverting the disease profiles with use of a computer program, an exhaustive differential diagnosis for each finding is obtained; these manifestation-based differential-diagnosis lists are retained as part of the knowledge base. The diagnostic program can use these lists to construct differential diagnoses in clinical cases.

How to group potential diagnoses into relevant problem areas is a separate consideration. The individual diseases in the INTERNIST-I knowledge base are part of a "disease hierarchy" that is organized from the general to the specific. For example, acute viral hepatitis is classified as a hepatocellular infection, hepatocellular infection is a subclass of diffuse hepatic parenchymal disease, and diffuse hepatic parenchymal disease falls into the category of hepatic parenchymal disease, which is a major subclass of diseases of the hepatobiliary system. Initially it was thought that access to the disease hierarchy would allow INTERNIST-I to construct appropriate differential diagnoses (i.e., problem areas) based on higher-level concepts such as hepatocellular infection. If several diagnoses representing types of hepatocellular infection were under consideration, it would be simple to create a problem area for hepatocellular infection. However, early experience with the system showed that a rigid hierarchical classification scheme was inadequate, since a single disease often merits simultaneous categorization under more than one heading. Infectious mononucleosis is both a hepatocellular infection and a type of infectious lymphadenopathy. Hierarchical classification would require that it be listed as one or the other, but not both. An additional concern is that diseases that present in a fixed manner in any one person may present differently in different patients. For example, alcoholic hepatitis may occur with a predominance of intrahepatic cholestasis in one patient and with massive hepatocellular necrosis in another. Solution of the classification problem entailed the development of algorithms (discussed below) that permit INTERNIST-I to construct problem areas in an ad hoc manner.

The building block for the INTERNIST-I knowledge base is the individual disease. For each diagnosis entered into the system, a disease profile is constructed. The disease profile consists of findings (historical items, symptoms, physical signs, and laboratory abnormalities) that have been reported to occur in association with the disease, including demographic data and predisposing factors. Two clinical variables are associated with each manifestation in an INTERNIST-I disease profile: an evoking strength and a frequency. The evoking strength answers the question, Given a patient with this finding, how strongly should I consider this diagnosis to be its explanation? The frequency is an estimate of how often patients with the disease have the finding. In addition, each manifestation is assigned a disease-independent import. The import is the global importance of the manifestation — that is, the extent to which one is compelled to explain its presence in any patient. Although the evoking strengths, frequencies, and imports are expressed as numbers (on a scale of 0 to 5 or 1 to 5) in the INTERNIST-I knowledge base, it is important to remember that they represent a shorthand for judgmental information, as their suggested interpretations in Tables 1 through 3 indicate. True quantitative information does not exist in the medical literature in most cases; the numbers used by INTERNIST-I are judgmental in that they are compiled after a review of the available knowledge.

The current INTERNIST-I knowledge base, which represents 15 person-years of work, encompasses over 500 individual disease profiles (an example appears in Table 4) and approximately 3550 manifestations of disease. The disease profiles have been generated by a review of the literature and by consultation with expert clinicians. In addition to the disease profiles, the knowledge base details relations among diagnoses and among manifestations. Within INTERNIST-I, im-

Table 1. Interpretation of Evoking Strengths.

Evoking Strength	Interpretation
0	Nonspecific — manifestation occurs too commonly to be used to construct a differential diagnosis
1	Diagnosis is a rare or unusual cause of listed manifestation
2	Diagnosis causes a substantial minority of instances of listed manifestation
3	Diagnosis is the most common but not the overwhelming cause of listed manifestation
4	Diagnosis is the overwhelming cause of listed manifestation
5	Listed manifestation is pathognomonic for the diagnosis

Table 2. Interpretation of Frequency Values.

Frequency	Interpretation
1	Listed manifestation occurs rarely in the disease
2	Listed manifestation occurs in a substantial minority of cases of the disease
3	Listed manifestation occurs in roughly half the cases
4	Listed manifestation occurs in the substantial majority of cases
5	Listed manifestation occurs in essentially all cases — i.e., it is a prerequisite for the diagnosis

portant high-level pathophysiologic states (such as acute left ventricular failure, chronic congestive left heart failure, prerenal azotemia, and chronic uremia) are profiled as if they were diseases. The knowledge base contains links between such "diseases" and other diseases. The links are used to express causality or a predisposition of patients with one disease to have another. Because INTERNIST-I formulates and resolves problem areas serially, it can piece together interdependent components of a multisystem illness one by one, using the links in the data base to promote consideration of diseases related to previously concluded diagnoses. The total number of links among the 500 diagnoses in the data base is about 2600. The 3550 manifestations in the INTERNIST-I knowledge base are not independent. Men do not have oligomenorrhea, and a patient with oligomenorrhea must be presumed to be female. The knowledge base includes the properties of each manifestation that specify how its presence or absence may influence the presence or absence of other manifestations. There are about 6500 such relations detailed in the knowledge base.

The Diagnostic Algorithms

The problem-solving algorithms represent the intellectual core of the INTERNIST-I system. Although the scoring mechanism described below manipulates probabilistic data (evoking strengths, frequencies, and imports), it must be emphasized that the behavior of INTERNIST-I results primarily from the application of two heuristic principles: the formation of problem areas through a partitioning algorithm and the conclusion of diagnoses within problem areas, using strategies such as diagnosis by exclusion.

Table 3. Interpretation of Import Values.

Import	Interpretation
1	Manifestation is usually unimportant, occurs commonly in normal persons, and is easily disregarded
2	Manifestation may be of importance, but can often be ignored; context is important
3	Manifestation is of medium importance, but may be an unreliable indicator of any specific disease
4	Manifestation is of high importance and can only rarely be disregarded as, for example, a false-positive result
5	Manifestation absolutely must be explained by one of the final diagnoses

The following steps are taken during an INTERNIST-I diagnostic consultation. (Please refer to the Appendix for an annotated sample case analysis taken from a CPC published in the *Journal*.[11])

(1) Initial positive (present) and negative (absent) findings in the patient are entered by the user. As each new positive manifestation is encountered, the program retrieves its complete differential diagnosis from the inverted disease profiles in the knowledge base. A "disease hypothesis" is created for each item on the manifestation's differential-diagnosis list. A master list of all such disease hypotheses is maintained. Higher-level concepts from the classification hierarchy are retained on the differential-diagnosis list as long as the diagnoses that they subsume are indistinguishable in their ability to explain the observed data. The master differential list therefore comprises all possible diagnoses that can explain any of the observed findings (taken either individually or in groups).

(2) For each disease hypothesis, four lists are maintained: all positive manifestations in the patient that are explained by the disease hypothesis (i.e., findings matching the disease profile stored in the data base); all manifestations that might occur in a patient with the disease but are known to be absent in the patient being considered; all manifestations that are present in the patient but are not explained by the disease hypothesis, i.e., not found on the disease profile (these manifestations represent either "red herrings" or items that would have to be explained by a second disease present in the patient); and manifestations that are on the disease's profile but about which nothing is known (this list is used in determining which questions to ask).

(3) Each hypothesis on the master list of diagnoses is given a score. Scores are calculated as the sum of a positive and a negative component as follows. The positive component includes the weights of all manifestations explained by the hypothesis, based on the evoking strengths of the observed manifestations for the diagnosis. A nonlinear weighting scheme is used: An evoking strength of 0 counts as 1 point, a strength of 1 counts as 4 points, a 2 counts as 10 points, a 3 counts as 20, a 4 as 40, and a 5 as 80. Any disease hypothesis related to a previously concluded diagnosis (through links in the data base) is given a bonus score. The bonus awarded is 20 points times the frequency number listed for the hypothesized diagnosis in the disease profile of the concluded diagnosis.

The negative component includes the weight of all manifestations that are expected to occur in patients with the disease but are absent in the patient under consideration. A nonlinear scale based on the expected frequency of the manifestation in the disease is used: A frequency of 1 counts as −1 point, a 2 as −4 points, a 3 as −7 points, a 4 as −15 points, and a 5 as −30 points. Also included are the weights of all manifestations present in the patient but not explained by the hypoth-

Table 4. A Sample Manifestations List.*

DISPLAY WHICH MANIFESTATION LIST?
ALCOHOLIC HEPATITIS

AGE 16 TO 25 . . . 0 1
AGE 26 TO 55 . . . 0 3
AGE GTR THAN 55 . . . 0 2
ALCOHOL INGESTION RECENT HX . . . 2 4
ALCOHOLISM CHRONIC HX . . . 2 4
SEX FEMALE . . . 0 2
SEX MALE . . . 0 4
URINE DARK HX . . . 1 3
WEIGHT LOSS GTR THAN 10 PERCENT . . . 0 3
ABDOMEN PAIN ACUTE . . . 1 2
ABDOMEN PAIN COLICKY . . . 1 1
ABDOMEN PAIN EPIGASTRIUM . . . 1 2
ABDOMEN PAIN NON COLICKY . . . 1 2
ABDOMEN PAIN RIGHT UPPER QUADRANT . . . 1 3
ANOREXIA . . . 0 4
DIARRHEA ACUTE . . . 1 2
MYALGIA . . . 0 3
VOMITING RECENT . . . 0 4
ABDOMEN BRUIT CONTINUOUS RIGHT UPPER QUADRANT . . . 1 2
ABDOMEN BRUIT SYSTOLIC RIGHT UPPER QUADRANT . . . 1 2
ABDOMEN TENDERNESS RIGHT UPPER QUADRANT . . . 2 4
CONJUNCTIVA AND/OR MOUTH PALLOR . . . 1 2
FECES LIGHT COLORED . . . 1 2
FEVER . . . 0 4
HAND(S) DUPUYTRENS CONTRACTURE(S) . . . 1 2
JAUNDICE . . . 1 3
LEG(S) EDEMA BILATERAL SLIGHT OR MODERATE . . . 1 2
LIVER ENLARGED MASSIVE . . . 1 2
LIVER ENLARGED MODERATE . . . 1 3
LIVER ENLARGED SLIGHT . . . 1 2
PAROTID GLAND(S) ENLARGED . . . 1 2
SKIN PALLOR GENERALIZED . . . 0 2
SKIN PALMAR ERYTHEMA . . . 1 3
SKIN SPIDER ANGIOMATA . . . 2 3
SKIN TELANGIECTASIA . . . 1 1
ALKALINE PHOSPHATASE BLOOD GTR THAN 2 TIMES NORMAL . . . 1 2
ALKALINE PHOSPHATASE BLOOD INCREASED NOT OVER 2 TIMES NORMAL . . . 1 4
BILIRUBIN BLOOD CONJUGATED INCREASED . . . 2 4
BILIRUBIN URINE PRESENT . . . 2 4
CHOLESTEROL BLOOD DECREASED . . . 2 2
CHOLESTEROL BLOOD INCREASED . . . 1 2
HEMATOCRIT BLOOD LESS THAN 35 . . . 1 3
HEMOGLOBIN BLOOD LESS THAN 12 . . . 1 3
KETONURIA . . . 1 2
PROTEINURIA . . . 1 2
SGOT 120 TO 400 . . . 2 3
SGOT 40 TO 119 . . . 2 3
SGOT GTR THAN 400 . . . 1 2
UREA NITROGEN BLOOD LESS THAN 8 . . . 2 2
UROBILINOGEN URINE ABSENT . . . 1 1
UROBILINOGEN URINE INCREASED . . . 2 4
WBC 14000 TO 30000 . . . 0 3
WBC 4000 TO 13900 PERCENT NEUTROPHIL(S) INCREASED . . . 0 3
WBC LESS THAN 4000 . . . 1 1
ACTIVATED PARTIAL THROMBOPLASTIN TIME INCREASED . . . 1 3
ANTIBODY MITOCHONDRIAL . . . 1 5
ANTIBODY SMOOTH MUSCLE . . . 2 3
BSP RETENTION INCREASED . . . 1 5
ELECTROPHORESIS SERUM ALBUMIN DECREASED . . . 2 4
ELECTROPHORESIS SERUM GAMMA GLOBULIN INCREASED . . . 2 4
FACTOR VII PROCONVERTIN DECREASED . . . 1 2
LDH BLOOD INCREASED . . . 1 3
MAGNESIUM BLOOD DECREASED . . . 2 2
PROTHROMBIN TIME INCREASED . . . 2 3
SGPT 200 TO 600 . . . 1 2
SGPT 40 TO 199 . . . 2 3
SGPT GTR THAN 600 . . . 1 1
LIVER BIOPSY BILE PLUGGING . . . 1 2
LIVER BIOPSY FATTY METAMORPHOSIS . . . 2 4

Table continues in next column.

LIVER BIOPSY FOCAL NECROSIS AND INFLAMMATION . . . 2 5
LIVER BIOPSY HEPATOCELLULAR NECROSIS MARKED . . . 2 3
LIVER BIOPSY MALLORY BODIES . . . 3 3
LIVER BIOPSY PERIPORTAL FIBROSIS MILD . . . 1 3
LIVER BIOPSY PERIPORTAL INFILTRATION NEUTROPHIL(S) . . . 3 5
LIVER BIOPSY PERIPORTAL INFILTRATION ROUND CELL(S) . . . 1 2
LIVER BIOPSY SMALL BILE DUCT(S) PROMINENT . . . 1 2

LINKS FOR ALCOHOLIC HEPATITIS:

Predisposes to	MALLORY WEISS SYNDROME . . . 1 1
Causes	SINUSOIDAL OR POSTSINUSOIDAL PORTAL HYPERTENSION . . . 1 2
Causes	HEPATIC ENCEPHALOPATHY . . . 2 2
Causes	RENAL FAILURE SECONDARY TO LIVER DISEASE <HEPATORENAL SYNDROME> . . . 2 2
Coincident with	PANCREATITIS ACUTE . . . 2 2
Precedes	MICRONODAL CIRRHOSIS <LAENNECS> . . . 2 3

*The first number after each manifestation is its evoking strength for the diagnosis, the second is the frequency of the manifestation in the disease.

esized diagnosis. The import (clinical importance) of each manifestation is used to assess this penalty: An import of 1 counts as −2 points, a 2 as −6 points, a 3 as −10 points, a 4 as −20 points, and a 5 as −40 points. The net score for any disease hypothesis is thus the sum of the above four component weights.

(4) After all disease hypotheses have been scored, the master list of all hypotheses is sorted by descending score. Diagnoses whose scores fall a threshold number of points below the topmost diagnosis are temporarily discarded as unattractive. They may be reconsidered, however, if further evidence obtained during the case analysis raises their scores above the threshold (relative to the topmost diagnosis).

(5) At this point, the sorted master differential-diagnosis list is a heterogeneous grouping of many disease hypotheses. A critical step in the diagnostic logic of INTERNIST-I is to delineate a set of competitors for the topmost diagnosis (i.e., to create a problem area containing the topmost disease hypothesis). Only one of the set of diseases in a properly defined problem area is likely to be present in a patient. Problem-area construction is carried out by the INTERNIST-I partitioner, which employs a remarkably powerful yet simple heuristic rule. The rule states, "Two diseases are competitors if the items not explained by one disease are a subset of the items not explained by the other; otherwise, they are alternatives (and may possibly coexist in the patient)." To paraphrase, if Disease A and Disease B, taken together, explain no more observed manifestations than either one does when taken alone, the diseases are classified as competitors. Competitors for the likeliest diagnosis are identified from the master differential list by the partitioning rule; including the topmost diagnosis, they constitute the "current problem area." Because INTERNIST-I defines problem areas in this ad hoc manner, its differential diagnoses will not always resemble those constructed by clinicians.

(6) Once the problem area containing the most attractive diagnosis has been selected, criteria for estab-

lishing a definitive diagnosis can be applied. If the problem area contains only the topmost diagnosis, INTERNIST-I will immediately decide on (conclude) that diagnosis. If there is more than one diagnosis in the problem area, INTERNIST-I directly concludes the leading diagnosis when its score is 90 or more points higher than the nearest competitor. The value of 90 was chosen because it slightly exceeds the weight carried by a pathognomonic finding (80 points). This method of concluding a diagnosis is a hallmark of INTERNIST-I. The absolute score of the diagnosis does not matter. The only point of importance is whether the diagnosis is sufficiently higher in score than its reasonable competitors (other diagnoses that explain the same set of findings).

(7) If it is not possible to conclude a diagnosis (which by default means that the current problem area contains more than one hypothesis), one of three questioning strategies is selected: "pursuing," "ruling out," and "discriminating." The pursuing mode is selected if the second best contender is 46 to 89 points behind the topmost diagnosis. In the pursuing mode, questions are asked to establish the topmost diagnosis, since it is close to fulfilling the criteria for conclusion. The questions asked are those that are most specific for the leading diagnosis (i.e., those with high evoking strengths). If there are five or more diagnoses within 45 points of the topmost diagnosis, the ruling-out mode is used. Questions that have high frequency numbers under the contenders are asked, with the expectation that several negative responses will remove some of the diagnoses from contention. The discriminating mode is used when there are two to four diagnoses within 45 points of the leading diagnosis. The questions asked attempt to maximize the spread in scores.

(8) In order to improve the efficiency of computations, questions are asked in small groups. The level of questioning is escalated (from history to physical-examination findings to gradations of laboratory results) only after the useful questions in a previous category have been exhausted. After the answers are processed, the disease hypotheses are again scored and partitioned. A new differential diagnosis is formed on the basis of the (possibly) new topmost diagnosis. This ad hoc method for constructing a differential diagnosis gives INTERNIST-I seemingly intelligent behavior, since the program will often change focus from one problem area to another when questioning in the first area has been counterproductive.

(9) When a diagnosis is concluded, all observed manifestations explained by the diagnosis are removed from future consideration. The program then recycles, using the remaining unexplained positive findings. Subsequent findings are marked as explained when a previously concluded diagnosis can account for them. However, it is not possible to undo a previous diagnostic conclusion when contradictory evidence becomes available.

(10) When a problem area contains more than one disease hypothesis and all useful lines of questioning have been exhausted (without meeting the criteria for concluding the topmost diagnosis), the program will defer making a diagnosis in that problem area. Diagnoses in the problem area are then displayed by descending score, along with an explanation that the differential diagnosis cannot be resolved.

(11) When all remaining manifestations have an import of 2 or less, the program stops.

An Evaluation of Internist-I

We have completed a preliminary evaluation of INTERNIST-I. The program was evaluated to compare its clinical acumen with that of human experts and to highlight its strengths and weaknesses. CPCs published in the *Journal* as Case Records of the Massachusetts General Hospital were used for the computer analysis. During the trial, only the published findings available to the case discussant were presented to INTERNIST-I (i.e., only findings mentioned before the presentation of the pathological findings). The knowledge base of INTERNIST-I was not altered during the course of the evaluation.

During the development of INTERNIST-I, hundreds of miscellaneous cases, both simple and complex, have been presented to the system in order to evaluate and improve the knowledge base and the diagnostic computer program. Since many of these test cases included *Journal* CPCs, cases for the trial were selected from 1969, a year from which no previous *Journal* cases had been presented to INTERNIST-I. Before entering any cases, project members serially reviewed the published final anatomic diagnoses. All cases in which one or more of the major diagnoses were not represented in INTERNIST-I's still incomplete knowledge base were rejected. The diagnostic program cannot conclude a diagnosis that is missing from the knowledge base; such a case would not be a fair test for the system. The excluded diagnoses were neither more rare nor more complex than the diagnoses chosen for analysis. Cases 1-1969 through 42-1969 (inclusive) were reviewed, and 19 cases were obtained in which all major CPC diagnoses were included in the data base. That only 19 of 42 cases reviewed qualified for the study is not unexpected. It is estimated that the current INTERNIST-I knowledge base includes roughly 70 to 75 per cent of the major diagnoses in internal medicine. If each case on the average contained three major diagnoses, the probability that all three diagnoses would be included in the knowledge base would be $(0.75) \times (0.75) \times (0.75)$ or 42 per cent.

In establishing criteria for evaluating performance on the *Journal* CPCs, one must classify final anatomic or clinical diagnoses as major or minor. Major diagnoses are defined as those central to the problem. Classified as minor diagnoses are diseases that were present in the patient but were clinically less relevant, including diseases only partially described in the

published case protocol, or conditions that were successfully managed and that subsequently resolved. Diagnostic decisions made by the clinicians at the Massachusetts General Hospital, by the case discussants, and by INTERNIST-I were classified as correct when they were confirmed by the pathologists or when a clinical syndrome was universally agreed to be present. When either the physicians or INTERNIST-I introduced an incorrect diagnosis, a separate notation was made, because an incorrect diagnosis has a different meaning from that of a failure to make a correct diagnosis. We recognize two ways for a program or a clinician to make a correct diagnosis in the setting of a CPC: to state unequivocally that the patient has the disease ("definitive diagnosis") or to offer an unresolved differential diagnosis that includes the correct diagnosis as its topmost element ("tentative diagnosis"). INTERNIST-I makes definitive diagnoses by conclusion and tentative diagnoses by deferral (see above). The hospital clinicians and the case discussants also made both types of diagnoses. A tentative diagnosis was counted as incorrect if its topmost element was not the correct diagnosis, even if the associated differential diagnosis included the correct diagnosis.

Table 5 summarizes the results in the 19 trial cases. There were 43 possible correct major diagnoses. INTERNIST-I, the clinicians at the Massachusetts General Hospital, and the case discussants made 17, 23, and 29 correct definitive diagnoses, respectively. A correct tentative diagnosis was offered eight, five, and six times, respectively. Thus, of 43 anatomically verified diagnoses, INTERNIST-I failed to make a total of 18, whereas the clinicians failed to make 15 such diagnoses and the discussants missed only eight. Of the 18 situations in which INTERNIST-I failed to make an anatomically correct diagnosis, the clinicians or the discussant or both failed to make the correct diagnosis 11 times. INTERNIST-I made a correct diagnosis in seven circumstances in which the clinicians or the case discussant or both failed to do so. INTERNIST-I made five incorrect definitive diagnoses and six incorrect tentative diagnoses (naming diseases that were not present in the patients). The Massachusetts General Hospital clinicians made eight incorrect definitive diagnoses and five incorrect tentative diagnoses. The case discussants made 11 incorrect definitive diagnoses and two incorrect tentative diagnoses. Four of the five situations in which INTERNIST-I made an incorrect definitive diagnosis were situations in which the discussant also made a wrong diagnosis.

The shortcomings of the program, which were highlighted by the evaluation, fall into two general categories. The first type are limitations due to the structure or content of the knowledge base. Examples include the absence of a manifestation required to describe an important finding; the use of overly simplistic manifestations for some circumstances; the inadvertent omission of a finding from a disease profile; the assignment of an incorrect evoking strength, frequency, or import; and the failure of a manifestation to convey adequate anatomic information. The second type of limitation resulted from deficiencies in the design or implementation (or both) of the computer program. Included in this category were the failure to incorporate temporal reasoning capabilities; problems resulting from the use of the scoring algorithm; the inability to take a broad overview in attacking a complex problem; and the improper attribution of findings to concluded diagnoses (i.e., invoking the wrong explanation for a finding). Specific reasons for INTERNIST-I's incorrect diagnoses (made both by omission and by commission) are listed in Table 6.

Table 5. Summary of Results for Major Diagnoses in 19 Cases Used in the INTERNIST-I Evaluation.

Category	Internist-I	Clinicians	Discussant
		no. of instances	
Total possible diagnoses	*43*	*43*	*43*
Definitive, correct	17	23	29
Tentative, correct	8	5	6
Failed to make correct diagnosis	18	15	8
Definitive, incorrect	5	8	11
Tentative, incorrect	6	5	2
Total no. of incorrect diagnoses	11	13	13
Total no. of errors in diagnosis	29	28	21

Discussion

Experience with INTERNIST-I has reinforced our impression of medical diagnosis as a complex process. Diagnosis consists of two fundamental activities: the generation of one or more differential diagnoses (each for a separate problem area) and the resolution of individual differential diagnoses. The surprising ability of the program to make multiple and complex diagnoses in the broad field of internal medicine emphasizes the power of its underlying heuristic methods.

Several important shortcomings of the INTERNIST-I approach to diagnosis merit further investi-

Table 6. Classification of Errors Made by INTERNIST-I during the Evaluation.

Type of error	No. of Occurrences
Knowledge-base errors	
Data base incomplete: omission	2
Data base incorrect	2
Lack of anatomic knowledge	1
Failure to represent degree of severity	2
Computer-program faults	
Lack of temporal reasoning	1
Failure of scoring algorithm	3
Failure to seek global overview	1
Improper attribution of a finding to a concluded diagnosis	6

gation. Feinstein[12] has emphasized the importance of explanation as part of diagnostic reasoning. INTERNIST-I's greatest failing during the evaluation (occurring in six instances) was its inability to attribute findings to their proper causes. Because of the ad hoc, serial nature of INTERNIST-I's formation of problem areas, the program cannot synthesize a general overview in complicated multisystem problems. The structure of the knowledge base, especially the form of the disease profiles, limits the program's ability to reason anatomically or temporally. The program cannot recognize subcomponents of an illness, such as specific organ-system involvements or the degree of severity of pathologic processes.

A diagnostic program must be able to recognize the appropriate cause or causes of observed findings in a patient. A justification for each diagnosis must be developed on a pathophysiologic or causal framework that is consistent with established medical knowledge. To its detriment, INTERNIST-I's handling of explanation is shallow. When the program concludes a diagnosis, that diagnosis is allowed to explain any observed manifestations that are listed on its disease profile. Once explained, a manifestation is no longer used to evoke new disease hypotheses or to participate in the scoring process. This situation is compounded by the inadequate representation of causality in the INTERNIST-I knowledge base. Disease profiles contain, in an undifferentiated manner, factors predisposing a patient to the illness as well as findings that result from the disease process itself. An example of this problem occurred in the analysis of Case 17-1969, when INTERNIST-I allowed hepatic encephalopathy to explain the finding of hypokalemia. The program should have recognized hypokalemia as a predisposing factor for hepatic encephalopathy and initiated a search for an independent cause of the finding. At present, the limitations of the knowledge base prohibit such activity.

What is required is a restructuring of the knowledge base to include intermediate-level pathophysiologic states and the segregation of predisposing factors from findings actually caused by a disease. Diseases should be profiled in terms of their intermediate states rather than as exhaustive lists of manifestations. If the program had such a feature, the presence or absence of each state would be independently determined, and a disease would be allowed to explain a finding only when the state causing the finding was confirmed.

A related problem not handled well by INTERNIST-I is the interdependency of manifestations. For example, persons with elevated conjugated bilirubin levels in their blood usually have bilirubinuria. At present, the evoking strengths of each finding count redundantly toward any diagnosis that can explain them. This phenomenon causes INTERNIST-I to favor disproportionately the most common explanation for a set of findings. A solution would be the creation of an intermediate-level state, "abnormal bilirubin metabolism and transport," which would explain both conjugated hyperbilirubinemia and bilirubinuria. Appropriate weight for the intermediate state (rather than for the interdependent manifestations) could be given to any diseases that cause it. Thus, the creation of a causal network of pathophysiologic states, interposed between observable manifestations and final diagnoses, would allow a diagnostic program to attribute findings to causes accurately and would help to diminish the influence of interdependent manifestations of disease.

INTERNIST-I constructs differential diagnoses in an ad hoc manner, using a scoring algorithm to define the topmost (best) diagnosis and another program, the partitioner, to define reasonable competitors for the topmost diagnosis. By formulating and focusing attention on only one problem domain at any given time, the program is able to disregard red herrings and to set aside temporarily findings caused by disease processes falling outside the selected problem domain. By creating and processing problem domains serially, the program is able to make multiple diagnoses. But INTERNIST-I cannot formulate a broad perspective in complicated multisystem problems. It is constrained to working with tunnel vision, discriminating among diagnoses within each problem area and remaining unable to look at several problem areas simultaneously. Only after a specific diagnosis is concluded can INTERNIST-I use the links in its data base to give bonus weight to related diagnoses in separate problem domains. New programming approaches to complex reasoning processes have been developed[8] to enable CADUCEUS, the successor to INTERNIST-I, to synthesize a broad overview incorporating causal relations into an approach to a patient's problems.

INTERNIST-I is unable to reason anatomically or temporally. The program could not differentiate gastric compression due to pancreatic mass effect from that due to hepatic mass effect in Case 23-1969, and in doing so it erroneously concluded that the patient had a hepatoma rather than pancreatitis. Nor can INTERNIST-I recognize the degree of severity of a finding or process in all instances. Two of INTERNIST-I's failures during the evaluation resulted from its inadequate recognition of the degree of severity of an individual manifestation (a decreased blood potassium level) and of an organ-system involvement by a pathologic process (disseminated vasculitis). Reorganization of the data base to allow representation of these concepts is also being undertaken.

INTERNIST-I is only one of many computer-based tools with the purpose of extending the capabilities of the physician. Such programs can broaden the clinician's scope and awareness of data for the diagnosis and treatment of illness. For the present, INTERNIST-I remains a research tool. After refinement of the knowledge base and diagnostic programs, a prospective clinical trial will be required to compare the program's behavior with that of clinicians in terms of diagnostic accuracy, cost effectiveness, and danger to the patient.

Appendix: A Sample Case Analysis

The transcript of an INTERNIST-I case analysis given below illustrates the operation of the diagnostic programs. The case was taken from a CPC published in the *Journal* in 1969.[11] The laboratory values are reported as measured in 1969. The bracketed paragraphs labeled "Comment" have been interpolated for clarification; they are not part of the actual consultation. Places where the transcript has been abridged are indicated by an ellipsis.

INTERNIST-I consultation SUMEX-AIM Version 15-May-81 07:31:39

ENTER CASE NAME: NEJM-CASE-30-1969-ADMISSION-1

[Comment: Here the user enters the initial positive findings (present in the patient) and negative findings (absent). The specialized INTERNIST-I vocabulary of some 3550 manifestations must be used in describing the case. The plus (+) prompt precedes each positive finding entered by the user. Because INTERNIST-I has no mechanism for the representation of time, all findings have been collapsed into a single list, independently of their order of appearance in the patient.]

INITIAL POSITIVE MANIFESTATIONS:
+AGE GTR THAN 55
+ARTHRITIS HX
+DEPRESSION HX
+SEX FEMALE
+THYROIDECTOMY HX
+ULCER PEPTIC HX
+URINE DARK HX
+WEIGHT INCREASE RECENT HX
+ANOREXIA
+CHEST PAIN LATERAL EXACERBATION WITH BREATHING
+CHEST PAIN LATERAL SHARP
+DYSPNEA ABRUPT ONSET
+ABDOMEN DISTENTION
+ABDOMEN FLUID WAVE
+ASTERIXIS
+FECES LIGHT COLORED
+JAUNDICE
+JOINT(S) PERIARTICULAR THICKENING
+JOINT(S) RANGE OF MOTION DECREASED
+LIVER ENLARGED MODERATE
+PLEURAL FRICTION RUB
+PULSE PRESSURE INCREASED
+SKIN PALMAR ERYTHEMA
+SKIN SPIDER ANGIOMATA
+SPLENOMEGALY SLIGHT
+TACHYCARDIA
+TACHYPNEA
+THYROID ENLARGED ASYMMETRICAL
+ALKALINE PHOSPHATASE BLOOD GTR THAN 2 TIMES NORMAL
+BILIRUBIN BLOOD CONJUGATED INCREASED
+BILIRUBIN URINE PRESENT
+FECES GUAIAC TEST POSITIVE
+GLUCOSE BLOOD 130 TO 300
+SGOT 120 TO 400
+AMMONIA BLOOD INCREASED
+ASCITIC FLUID PROTEIN 3 GRAM(S) PERCENT OR LESS
+ASCITIC FLUID WBC 100 TO 500
+ELECTROPHORESIS SERUM ALBUMIN DECREASED
+ELECTROPHORESIS SERUM BETA GLOBULIN INCREASED
+ELECTROPHORESIS SERUM GAMMA GLOBULIN INCREASED
+GLUCOSE TOLERANCE DECREASED
+IMMUNOELECTROPHORESIS SERUM IGA INCREASED
+IMMUNOELECTROPHORESIS SERUM IGM INCREASED
+IMMUNOELECTROPHORESIS SERUM IGG INCREASED
+LDH BLOOD INCREASED
+LE TEST POSITIVE
+LIVER RADIOISOTOPE SCAN IRREGULAR UPTAKE
+PROTHROMBIN TIME INCREASED
+RHEUMATOID FACTOR POSITIVE
+STOMACH BARIUM MEAL HIATAL HERNIA
+*DENY*

[Comment: The key word DENY indicates to INTERNIST-I that the user now wants to enter negative findings. The minus (−) prompt precedes each negative finding entered.]

INITIAL NEGATIVE FINDINGS:
−ALCOHOLISM CHRONIC HX
−DIARRHEA CHRONIC
−FECES BLACK TARRY
−FEVER
−PRESSURE VENOUS INCREASED ON INSPECTION
−HEMATOCRIT BLOOD LESS THAN 35
−UREA NITROGEN BLOOD 30 TO 59
−URIC ACID BLOOD INCREASED
−ASCITIC FLUID AMYLASE INCREASED
−ASCITIC FLUID CYTOLOGY POSITIVE
−ASCITIC FLUID LDH GTR THAN 500
−ESOPHAGUS BARIUM MEAL VARICES
−STOMACH BARIUM MEAL ULCER CRATER
−T3 RESIN UPTAKE INCREASED
−T4 TOTAL BLOOD INCREASED
−*GO*

[Comment: The user enters *GO* to indicate that all relevant positive and negative findings have been entered. The INTERNIST-I consultant programs guide the user through the rest of the diagnostic workup by asking questions. For clarity, all responses typed by the user from this point on will be in italics.]

DISREGARDING: DEPRESSION HX, WEIGHT INCREASE RECENT HX, CHEST PAIN LATERAL EXACERBATION WITH BREATHING, CHEST PAIN LATERAL SHARP, DYSPNEA ABRUPT ONSET, ABDOMEN FLUID WAVE, ASTERIXIS, JOINT(S) PERIARTICULAR THICKENING, PLEURAL FRICTION RUB, THYROID ENLARGED ASYMMETRICAL, FECES GUAIAC TEST POSITIVE, GLUCOSE BLOOD 130 TO 300, AMMONIA BLOOD INCREASED, ASCITIC FLUID PROTEIN 3 GRAM(S) PERCENT OR LESS, ASCITIC FLUID WBC 100 TO 500, GLUCOSE TOLERANCE DECREASED

CONSIDERING: AGE GTR THAN 55, SEX FEMALE, URINE DARK HX, ANOREXIA, FECES LIGHT COLORED, JAUNDICE, LIVER ENLARGED MODERATE, SKIN PALMAR ERYTHEMA, SKIN SPIDER ANGIOMATA, SPLENOMEGALY SLIGHT, ALKALINE PHOSPHATASE BLOOD GTR THAN 2 TIMES NORMAL, BILIRUBIN BLOOD CONJUGATED INCREASED, BILIRUBIN URINE PRESENT, SGOT 120 TO 400, ELECTROPHORESIS SERUM ALBUMIN DECREASED, ELECTROPHORESIS SERUM GAMMA GLOBULIN INCREASED, IMMUNOELECTROPHORESIS SERUM IGA INCREASED, IMMUNOELECTROPHORESIS SERUM IGG INCREASED, IMMUNOELECTROPHORESIS SERUM IGM INCREASED, LDH BLOOD INCREASED, LE TEST POSITIVE, LIVER RADIOISOTOPE SCAN IRREGULAR UPTAKE, PROTHROMBIN TIME INCREASED, RHEUMATOID FACTOR POSITIVE DISCRIMINATE HEPATITIS CHRONIC ACTIVE, BILIARY CIRRHOSIS PRIMARY

[Comment: At this point, INTERNIST-I has constructed a master differential-diagnosis list, ordered its members with a scoring algorithm, and then focused attention on the most promising problem area, which appropriately contains two liver diseases. The DISREGARDING list consists of all findings that are inconsistent with the topmost (first-listed) diagnosis; the CONSIDERING list includes all findings explained by the topmost diagnosis (i.e., chronic active hepatitis). The number of plausible contenders in the problem area determines the strategy for questioning. Questions are asked to discriminate between the two diagnoses.]

Please Enter Findings of LIPID(S) BLOOD:
GO
CHOLESTEROL BLOOD DECREASED?

N/A

[Comment: INTERNIST-I asks questions in two forms. A question of the style "Please Enter Findings of . . . ." asks about a generic class of findings, such as serum lipids or chest x-ray films. The user enters specific (positive or negative) findings and when finished types *"GO."* If there are no positive or negative findings to enter, typing *"GO"* will cause the programs to ask the original single item that prompted the generic question. For example, an elevated cholesterol level would favor primary biliary cirrhosis over chronic active hepatitis, whereas the converse situation would apply if the cholesterol were decreased. Thus, INTERNIST-I asked a generic question about serum lipids. The second form of questioning is direct. INTERNIST-I simply prints a manifestation name followed by a question mark. The user can then respond by typing *"YES"* (present), *"NO"* (absent), or *"N/A"* (not available — either unknown or not performed). The published CPC did not mention the serum cholesterol value, so the user entered *N/A*.]

Please Enter Findings of INSPECTION AND PALPATION SKIN

GO

SKIN XANTHOMATA?

NO

Please Enter Findings of BLOOD COUNT AND SMEAR

GO

RBC TARGET(S)

NO

[Comment: INTERNIST-I uses information about the type of each manifestation — history, symptoms, signs, and laboratory tests, both routine and two gradations of more expensive or invasive laboratory procedures. The types of manifestations determine which questions are asked. Although the greatest discriminating power for resolving a differential diagnosis often resides in an invasive test, such as a liver biopsy, INTERNIST-I has been programmed to exhaust the useful history and physical-examination findings before escalating its questioning to more expensive or dangerous laboratory tests.]

Please Enter Findings of KIDNEY FUNCTION TEST(S)

GO

UREA NITROGEN BLOOD 60 TO 100?

NO

UREA NITROGEN BLOOD GTR THAN 100?

NO

Please Enter Findings of LIVER FUNCTION TEST(S)

GO

UROBILINOGEN URINE ABSENT?

N/A

[Comment: INTERNIST-I did not seek to investigate renal function itself in the passage above. It was programmed to recognize that the urinary urobilinogen value may be unreliable in the presence of marked azotemia, so it first asked about the blood urea nitrogen.]

CONCLUDE: HEPATITIS CHRONIC ACTIVE

[Comment: It is likely that INTERNIST-I had nearly made the diagnosis of chronic active hepatitis before it asked any questions. The negative answers favored chronic active hepatitis, and therefore INTERNIST-I concluded the diagnosis. The programs now recycle, using the findings not explained by the concluded diagnosis.]

DISREGARDING: DEPRESSION HX, CHEST PAIN LATERAL EXACERBATION WITH BREATHING, CHEST PAIN LATERAL SHARP, DYSPNEA ABRUPT ONSET, ASTERIXIS, JOINT(S) PERIARTICULAR THICKENING, PLEURAL FRICTION RUB, THYROID ENLARGED ASYMMETRICAL, FECES GUAIAC TEST POSITIVE, GLUCOSE BLOOD 130 TO 300, AMMONIA BLOOD INCREASED, GLUCOSE TOLERANCE DECREASED

CONSIDERING: WEIGHT INCREASE RECENT HX, ABDOMEN DISTENTION, ABDOMEN FLUID WAVE, ASCITIC FLUID OBTAINED BY PARACENTESIS, ASCITIC FLUID WBC 100 TO 500, ASCITIC FLUID PROTEIN 3 GRAM(S) PERCENT OR LESS

CONCLUDE: TRANSUDATIVE ASCITES

DISREGARDING:

CONSIDERING: ASTERIXIS, PULSE PRESSURE INCREASED, TACHYCARDIA, AMMONIA BLOOD INCREASED

PURSUING: HEPATIC ENCEPHALOPATHY

[Comment: The links in the INTERNIST-I data base between chronic active hepatitis and hepatic encephalopathy have resulted in a bonus weight's being given to hepatic encephalopathy here; previously, links had promoted the consideration of transudative ascites, since it can also be caused by chronic active hepatitis.]

CSF FLUID OBTAINED?

N/A

[Comment: Here INTERNIST-I was about to ask about the glutamine level in the cerebrospinal fluid. Since no lumbar puncture was performed, the result is not available.]

CONCLUDE: HEPATIC ENCEPHALOPATHY

[Comment: In the above situation, there were no diagnostically helpful tests remaining for INTERNIST-I to ask. INTERNIST-I has been programmed to relax its criteria for concluding a diagnosis when all useful lines of questioning have been blocked. Since INTERNIST-I had been close to making the diagnosis of hepatic encephalopathy, the program now concludes the diagnosis. The case analysis was intentionally stopped at this point, because all relevant major diagnoses had been covered. Without such intervention, INTERNIST-I would try to explain any remaining important findings, such as the arthritis and pleurisy.]

We are indebted to Craig D. Dean, Charles E. Oleson, and Kenneth W. Quayle for their contributions in writing the INTERNIST-I computer programs; to Zachary C. Moraitis for his assistance in the conceptual design of the project and in the development of the knowledge base; to a large number of medical students and several fellows in computer medicine for their assistance in the development of the INTERNIST-I knowledge base; and to the staff of the SUMEX-AIM computing facility of the National Institutes of Health for providing expert assistance and a friendly environment for programming.

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Mr. VOLKMER. What we will do is complete all the panel's testimony and then proceed to questions.

Thank you very much, Dr. Myers.

Dr. Gardner.

Dr. GARDNER. Thank you, Mr. Chairman.

I'm going to show some slides. So I'll get a mike on here.

Mr. VOLKMER. All right.

[Slide 1 shown.]

Dr. GARDNER. To give you a flavor for what a hospital in 1986 might look like, this is a picture taken in our shock/trauma intensive care unit. The patient is hidden, almost, by the equipment; a nurse taking care of the patient; the bedside monitoring equipment; ventilators; computer terminals; IV pumps——

Mr. PACKARD. Could you stand on the other side, please?

Dr. GARDNER. Yes.

So there's a variety of equipment connected to the patient's bedside, and each of these modules contains a computer and, in addition to a computer terminal here (Dr. Gardner pointed to the right side of slide 1), that communicates with the central data system.

[Slide 2 shown.]

The HELP system is an outgrowth of about 15 or 20 years of work. To begin with, we spent our time primarily collecting patient data. After a few years, it became apparent to us that merely collecting and reporting data was a nice activity, but making decisions from it was even more important.

So we now have data coming from the intensive care units to this medical decisionmaking system, laboratories, other special places like the admitting office. So there's an integrated hospital information system.

As data comes from the intensive care unit or the laboratory, the computer applies its knowledge base to that information and makes decisions or interpretations or provides alerts to physicians as they're caring for the patient.

We have access outside the hospital, and that took us about 9 months of legal interaction with our hospital attorneys in order to provide security of that system outside the hospital.

We thought of callback schemes. Unfortunately, the phone company provides call forwarding, so that didn't work. So the thing we have come up with is a system. We issue each of the physicians who has this capability a floppy disc which has their code encoded on it, so basically it's a key to the system. We keep track of when they call in, which patient data they look at, so we have a log in addition to a legal signature indicating that they won't share the key with others.

[Slide 3 shown.]

If we look at the variety of data that comes in, we have summarized, this is an intensive care report; it tells us who the patient is here—that's been blocked out—laboratory data, and here we have some blood gas information that says there's a normal acid-base chemistry, the hyperventilation is corrected, and that the patient has a mild hypoxemia.

This is an indication of raw data that's entered into the computer from laboratory instruments or the bedside, and the interpretation is automatically provided by the computer.

[Slide 4 shown.]

These reports, then, are used in the medical decisionmaking process. Here is Dr. Clemmer who runs the shock/trauma unit. In teaching rounds each morning, he uses the data from this to review and care for the patient.

[Slide 5 shown.]

This is an example of a typical medical chart showing respiratory therapy data which is hand entered, and if you work at it, you can interpret some of it.

[Slide 6 shown.]

This is an example—you may not be able to see it in the back—but of a similar type of thing with respiratory therapists entering the data into the computer. From this data entry we get a clearly readable form, we improve the quality of the record, and the patient's billing information and the technician's efficiency are evaluated from this type of data entry.

[Slide 7 shown.]

We looked at the quality of the respiratory therapy charting, and signature, medications, comments, a variety of things, and in every case the computer improved the quality of the charting in reviewing over 500 charts.

[Slide 8 shown.]

We then said, well, what does it do to the efficiency of the respiratory therapy department, and we did a before and after study, and, to our surprise, the efficiency of the respiratory therapy department increased by about 15 percent, which for our hospital represented over a quarter of a million dollars a year savings.

[Slide 9 shown.]

A question that frequently we are asked: Are we frightened about the legal consequences of having the computer make medical decisions? As part of the process of the knowledge base or the information that's used for making decisions, we very closely couple with our physicians, and they provide the medical knowledge. We go through a validation process which involves, first, trying the knowledge base on known cases and go through several iterations as we, if you will, debug these types of programs.

We then go through a phase when we put the decision criteria out and have our group or expert panel review the data to help us validate it. Now the physicians really consider this part of their activity, and so the knowledge base is theirs, not mine as a computer scientist.

[Slide 10 shown.]

Should the medical knowledge be treated as a medical device in a legal sense as the FDA would do that? I would hope not at this point. Deriving medical knowledge from physicians is a very tedious and difficult task. They're not used to thinking—in general, physicians aren't used to thinking in logical and structured terms, and setting up decision criteria for interpretations and so on is already very difficult. We'd hate to see legislation—I would hate to see legislation come along which would make that task even more difficult.

[Slide 11 shown.]

Can computerized medical decision support systems reduce medical care costs or improve patient care? And I maintain with some

of the studies that we've done and some that Dr. McDonald has done that we can not only increase the quality of medical care but we can also reduce the costs in providing that care.

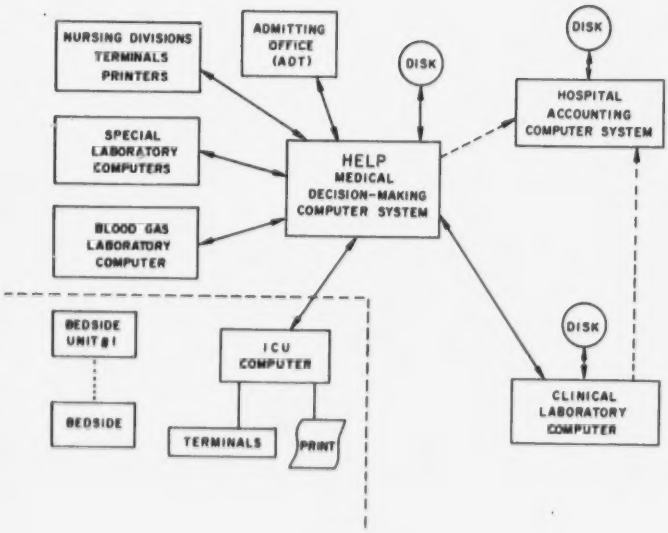
Computers are here. Like I showed at that bedside, there are probably 10 or 15 computers at the bedside. Let's make optimum use of them and not wait or not be hung up with legislation which would cause us difficulties in further using the new computer technology.

That's the last one. If we could have the lights on.

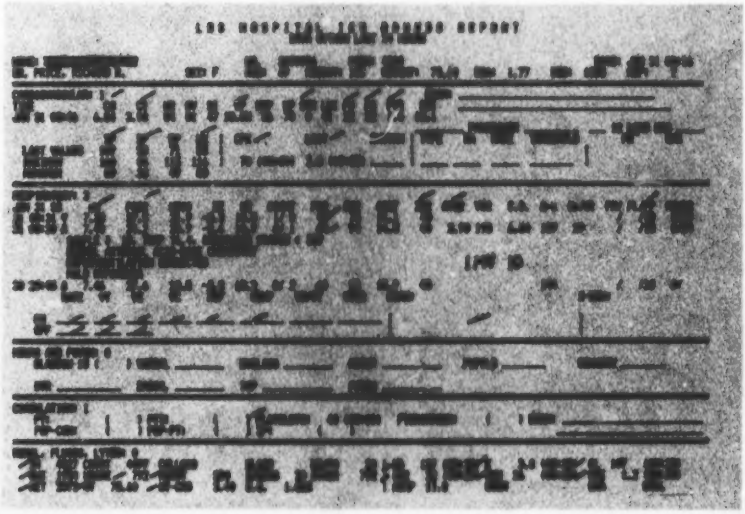
Thank you.

[Slides 1 through 11 of Dr. Gardner's oral presentation plus his prepared statement follows:]

SLIDE 1



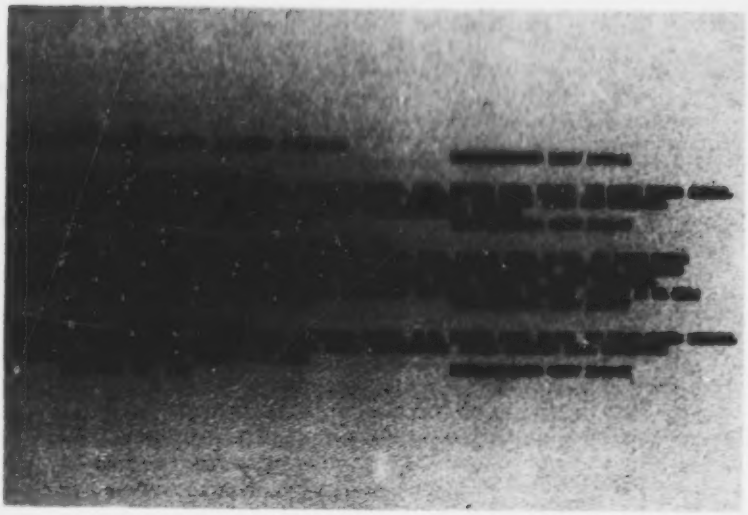
SLIDE 2



SLIDE 3

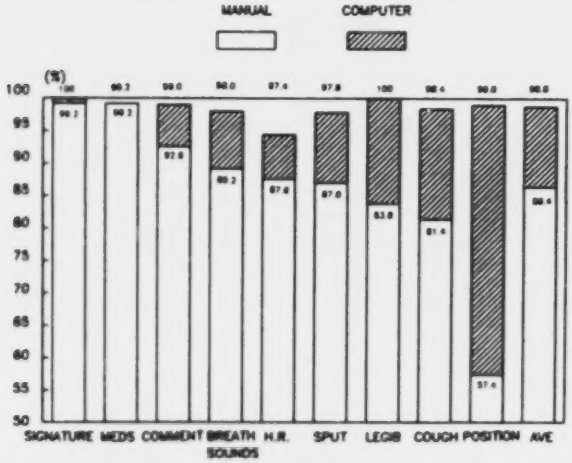
SLIDE 4

SLIDE 5



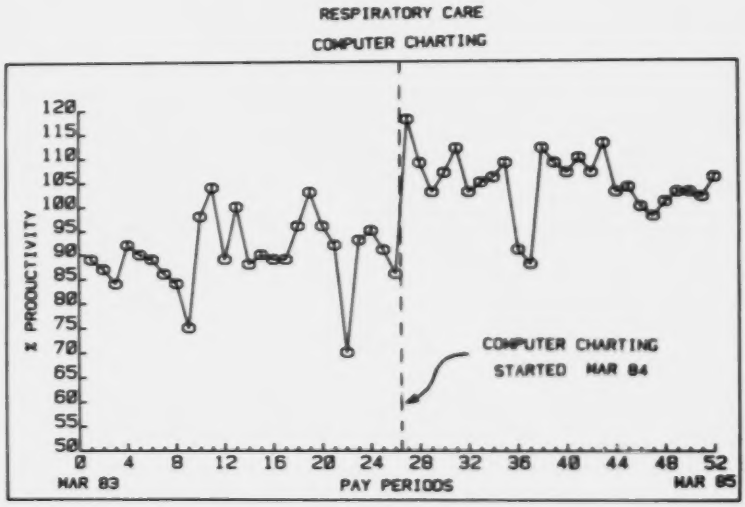
SLIDE 6

QUALITY AND CONTENT OF
RESPIRATORY THERAPY CHARTING



Percentages of acceptable charting from an audit of 500 procedures of manual charting and 500 procedures of computer charting. Numbers atop bars are percentages of acceptable computer charts; numbers in bars are percentages of acceptable manual charts.

SLIDE 7



SLIDE 8

3. ARE WE FRIGHTENED ABOUT THE LEGAL CONSEQUENCES OF HAVING THE COMPUTER MAKE MEDICAL DECISIONS?

SLIDE 9

4. SHOULD MEDICAL KNOWLEDGE BE TREATED AS A "MEDICAL DEVICE" IN THE LEGAL SENSE SUCH THAT THE FDA WOULD REGULATE IT AND CONTROL ITS IMPLEMENTATION?

SLIDE 10

5. CAN COMPUTERIZED MEDICAL DECISION SUPPORT SYSTEMS REDUCE MEDICAL CARE COSTS OR IMPROVE PATIENT CARE?

SLIDE 11

Statement for House Subcommittee on Investigations & Oversight
of the Committee on Science and Technology
March 18, 1986

HELP

A Medical Expert System
LDS Hospital, Salt Lake City, Utah
Reed M. Gardner, PhD

Overview:

Larry, a 30-year-old man critically injured in an automobile accident, is admitted to our trauma center. Using a computer, medical emergency staff order and receive the results of laboratory tests at electronic speed. Once doctors have determined the extent of his serious head, chest, and abdominal injuries, the patient is brought to surgery, then later moved to a shock/trauma intensive care unit (ICU). Here, a computer monitors Larry's heart rate, rhythm, and blood pressure. A computerized ventilator supports his breathing and computerized infusion pumps control drug and fluid infused into a vein to maintain his blood pressure.

After two days of improvement, however, the computer, using data from X-Ray and the laboratory, finds that Larry has pneumonia. These data were automatically communicated from computers in the X-Ray department and laboratory to the central HELP computer system. Further, the computer results show a still worse situation; Larry has multiple organs failing - heart, lung, and kidneys. Using the computer to sustain his metabolism, his doctor prescribes intravenous feeding. The computer guides the doctor through the ordering process, making certain that Larry gets no drugs which he is allergic to, nor that his medical functions will not handle. Laboratory results are used by the computer to "guide" the staff by suggesting appropriate treatment. Larry's physician and nurse use the computer to collect, organize, and interpret his data, which includes clinical notes and observations. As a result, they seldom need to "scribble" notes on the chart.

At morning rounds when the physician and nursing team caring for Larry independently review and assess his status, using a series of computer produced summary reports with computer generated prompts and interpretations. The computer report organizes the data by organ system. Discussion of Larry's status at rounds is lively, since all members of the care team can have a complete picture of the patient's state.

The computer also generates summary reports for each nursing shift and each day showing the patient's progress over a week. These computerized assists help the physicians and nurses caring for Larry, while simultaneously logging all the data for administrative (billing) and medical-legal functions.

Care of critically ill patients requires considerable skill and prompt, accurate treatment decisions. Physicians and nurses

collect a great deal of data through frequent observations, regular testing, and continuous monitoring of critically ill patients. As a result, the physicians can miss important events and trends unless the mass of accumulated data is presented in a compact, well-organized form. Economic pressures to reduce the use of therapeutic and diagnostic resources compound the physician's difficulties in caring for hospitalized patients.

History:

We have developed the HELP (Health Evaluation through Logical Processing) medical computing system over the last 14 years, and it is now available as a commercial product from Control Data Corporation. The system had its beginnings in the experimental physiological laboratory. We found that techniques developed for sophisticated experiments were applicable to patient care. Therefore we started applying the techniques in the heart catheterization laboratory and soon were using the computer to monitor open heart surgery patients; next computers were used in intensive care units and finally were applied to all hospital patients. It soon became apparent that collecting and reporting patient data was important, but we then realized the computer had greater capabilities of making decisions from the data stored in its memory. After coming to this realization, we undertook the development of a computerized decision making system. We call our system a decision support system. Other titles it might be given are Expert System, Knowledge Base System, or Artificial Intelligence System.

Protection of Patient Data/Privacy:

Care of hospitalized, especially critically ill, patients requires high levels of communication between teams of physicians, nurses, technicians, clerks, and support staff. As a result one of the major functions performed by the HELP system is to make information available quickly and conveniently for this health care team. One of the theoretical concerns about such a system is that it will "invade the patient's privacy". To protect against this invasion of privacy we originally developed a very sophisticated computer log-on scheme to be used by physicians and staff. It soon became apparent that the problems of hospitals were not of having too much data available, but of having too little and having the data delayed. Therefore, the medical staff, led by our chief of surgery,took the administrative steps to make the system easier to use and more accessible. We used the criterion that the computerized patient record should be as accessible as the conventional "paper chart". Computer security is provided primarily by having the terminals maintained in a secure location. Staff working in the computer area and graduate students are instructed to maintain patient privacy and sign a form indicating that they won't release patient information.

Any physician can review information on any patient, just as with the paper record. This type of open access is required,

since from minute to minute the care of acutely ill patients can require the assistance of a new specialist. Free access to patient data without administrative overhead is essential. If a simple scheme is not available, physicians would just call the laboratory, X-Ray department, or nurses and have the data given to them over the telephone. Over ten years of use of the system with this rather open access method has not resulted in any major breach of privacy or legal challenge. On the other hand, availability of paper records continues to be a problem. Recently a local official was in the hospital and to protect the patient's privacy the record was put in his room. The computer had the patient registered with an alias to prevent unauthorized review. The computer record in this case was much more secure than the conventional paper record.

Recently we made patient records accessible via telephone to physicians who had personal computers in their homes or offices. Because of the potential for increased access and the possibility of unauthorized access to patient records, in concert with the medical, administrative and legal staffs of the hospital we established a six level security system for remote access:

1. Access is only provided to those who sign a legal agreement to get a system "key" which makes the signer responsible for any access using the "key".
2. The "key" is a floppy disk which has "hidden" logon codes contained on it.
3. Access to the HELP system is only available through an unpublished telephone number.
4. Passwords and log-on codes included in the "key" must be entered promptly and in proper order for the user to get access.
5. Users currently have limited access to review patient records. In the future we will explore the possibility of ordering patient tests from remote locations. The conventional telephone is used for that purpose now.
6. Each remote interaction is logged by the computer which keeps track of who used the system, when they used it, and which patient's data they accessed.

The major problem in setting up this six level telephone access system was legal, not technical.

When a health care provider is located in the hospital, the HELP system does not limit access to patient data by class of provider, much as the conventional paper record does not restrict access. Physicians, nurses, and technicians have access to the patient data from terminals located on the nursing division. Admitting clerks, X-Ray clerks and similar staff do not have options to review most clinical data. Remote access is provided only to physicians. We have not yet had legal or security challenges to our computerized medical records. On the other hand, security of the conventional paper records are a continual problem.

Validation of decision-making software and related legal issues:

60-803 0 - 86 - 2

Since our computer system interprets the patient data, we are frequently asked if we have malpractice insurance for our computer system. We do not. However, we take great care to validate the accuracy of the patient data which is entered into the system and then implement decision criteria that are validated by our medical staff. One has to understand that the decisions we are making are not "magic" but are currently based on common sense criteria agreeable to physicians. In this early stage of the development of our medical decision support system, we are only working on rather simple interpretive and alerting criteria. Two examples of how medical knowledge is prepared for use by the computer should allay any fears of the computer "taking control":

1. In cooperation with the pulmonary division, we developed criteria for interpretation of lung function and blood gas results. The first set of criteria were selected from printed materials used to train new pulmonary physicians. A careful review of these criteria showed there were several situations which the logic did not cover and others in which their logic was flawed. As a result a team of physicians and knowledge engineers set out to correct the problems. As a result a regional conference was held at which the "rules" for data gathering and interpretation were agreed upon. The computer provided much of the information needed for evaluation of the proposed decision criteria. The result of this effort was the publication of a manual for uniform laboratory testing and interpretation. Physicians welcomed the opportunity to refine their decision making skills. The manual has recently undergone a careful review and is in its second edition. The computer implements the criteria published in the manual.
2. We have recently set up computerized review methods to promptly alert physicians and nurses about life threatening laboratory results. To determine the appropriate alerting criteria we invited a group of 6 physicians to independently establish the criteria they felt were important. After summarizing each of their criteria we held a group discussion with them and established a group consensus. The entire process was very enlightening, because of the diversity of interests and criteria. However, we were able to come to a consensus and are now implementing the computerized alerting criteria.

Extracting medical decision criteria from the medical literature and the medical staff is a very time-consuming and difficult task. We have developed computer criteria which seemed very logical and helpful, but turned out to be useless.

When we implement computerized medical rules on the HELP system simulated patient data is used to validate the decision rules. After review of this simulated data we make corrections and rerun the simulated data. Then, using the data already available in the computer system, we analyze the data from

several hundred patients. Each patient record is reviewed and the criteria checked by knowledge engineers as well as physicians. Several questions about the implications of computer aided medical decision-making arise:

Do we need to have malpractice insurance for our system?

At the moment the computer performs no direct action on the patient, but serves primarily as a "safety net" for the medical staff.

Are we concerned about the legal consequences of having the computer make medical decisions?

Any concern should be centered around two issues: 1) Invalid medical knowledge or errors in the computer implementation of the knowledge. Our computerized decision support system has been set up with the encouragement of the hospital medical and administrative staff. The system is "theirs". As a result we are giving them feedback and interpretations on the medical situations they want. 2) Concerns about what happens if the computer is not available have been minimized by having a high reliability system (up 99.5% of the time). This question is similar to asking if a high wire performer is safer with or without a safety net.

Should the medical knowledge be treated as a "medical device" in the legal sense such that the FDA should regulate it and control its implementation?

At the moment such a step would dramatically restrain the development and application of technology which is just starting. If the same FDA medical device criteria were applied to medical journal articles when new knowledge is presented, research articles would be delayed for publication for at least 5 years and medical research would stagnate. Fortunately the first amendment assuring freedom of speech and press protects the published medical literature. Computerized decision support programs are not much different than a physician taking the newest literature on a subject and applying it to their patient. The one exception to this rule which comes to my mind is the patient who is connected to a "closed loop" controller which may maintain blood pressure or other body function by infusing a drug.

Control Data Corporation (CDC) is now marketing our system. They have chosen to leave the transfer and development of the medical knowledge base to the medical staffs of the hospitals where they have sold the HELP system. By taking this step CDC has taken itself out of the "practice" of medicine and put it squarely in the hands of the medical staffs of their hospitals. Most of these hospitals have used the decision criteria developed at the LDS Hospital as a starting point. Appropriate modifications are made to fit the local situation for such things as altitude, patient mix etc..

We are just at the beginning of an exciting and effective development in the area of computer assisted medical decision-making. The use of such systems provide better patient care at reasonable cost.

Mr. VOLKMER. Does that conclude your oral testimony?

Dr. GARDNER. That concludes my—yes.

Mr. VOLKMER. Thank you very much, Dr. Gardner.

Mr. Baker.

Mr. BAKER. Chairman Volkmer, I would like to address the questions as were [2] outlined in the invitation to be a witness.

The short history that I have to work with in the—taking these to market began in 1984. My first problem was to find venture capital. I was fortunate enough to be the subject of a vignette in one of the weekly business magazines, and that problem went away.[3]

The next problem that came up was—I think you heard Dr. Myers talk about the system—his system being a prototypical system; you talked about it being. The systems that we're interested in marketing—at Yale in hypertension, at the University of Missouri in rheumatology, and Dr. Myers' system in internal medicine—are all prototypical. In fact, the rheumatology system keeps—the technology that they're developing keeps moving out from under our ability to determine what its market would be. The computer hardware is moving very fast. These groups are taking advantage of it. The artificial intelligence techniques are maturing, and they're taking advantage of those.[4]

I have sort of a moving target out there for products. I don't have a product yet. So that's my problem. Maybe if these people—the academic physicians—had a little bit tougher time financially, they'd be more eager to move from the prototypical stage to the commercial stage.[5]

In taking these systems to the marketplace, there are several mandatory steps that have to be done.[6] The validation of the medical knowledge and the processes of making the decisions has to be done, and it has to be done on a national basis. I believe you know that the National Institutes of Health has for human consultants a series of consensus development programs, and they have it in many, many disease areas.[7]

Well, we have to provide a way of doing the initial validation of the knowledge base so it does represent what's best at the current state of knowledge in the country, not just at one given institution,

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[2] Mr. Baker requested the deletion of the world "were."

[3] Mr. Baker changed this paragraph to read, "The short history of my experience in taking artificial intelligence products to market began in 1984. My first problem was to find venture capital. I was fortunate enough to be the subject of a vignette in one of the weekly business magazines, and that problem was resolved."

[4] Mr. Baker changed this paragraph to read, "The next problem that came up was tying down clinical products. You heard Dr. Myers talk about his system, CADUCEUS, being a prototypical system. The systems that we are interested in marketing, for Yale in hypertension, from the University of Missouri in rheumatology, and Dr. Myers system in internal medicine, are all prototypical. In fact the rheumatology project keeps advancing. The technology that they are developing keeps moving out from under our ability to determine what its market would be in terms of the number of physician users for each system. Computer hardware is moving very fast in capability and reduced costs. These groups are taking advantage of these advances. Also, the artificial intelligence techniques are maturing, they are taking advantage of those new methods."

[5] Mr. Baker changed this paragraph as follows: "I have sort of a moving target out there for potential products. I don't have a product yet. So that's my problem. It may be if these people, the academic physicians, had a little bit tougher time financially, they would be more eager to move from the prototypical stage to the commercial stage."

[6] Mr. Baker changed the word "done" to "accomplished."

[7] Mr. Baker revised this sentence to read, "I believe you know that the National Institutes of Health has conducted, for human specialists, a series of consensus development programs in many disease areas."

and then, after it goes through the marketplace, we have sort of a continuing education problem to look after.[8]

I believe Dr. Myers' system needs to be updated about every two months with the new knowledge that's come in about the diseases that he's working with. Before that can be incorporated into the system, it has to be examined in terms of how it changes the total system. It's a ripple effect as this new knowledge flows into it.[9]

So there's an ongoing responsibility of the community, and especially the organization marketing these things, to provide this valid, dynamic activity, and, I'll repeat again, it's like a continuing medical education of the computer expert and analogous to that of the human.

So that's how I think we would—well, that is how we will assure that it operates in the best way possible.[10]

The relationship—my relationship with the Food and Drug Administration has been very informal. I have some contacts there. I have seen some of the reports. I think they generated a report in 1982 dealing with computers in medicine.[11] It focused primarily on those systems where there is no human intervention involved between the computer and the patient.[12]

I wish they had made that very simple distinction in the paper that they submitted for this hearing, that there is a big difference between a computer embedded in a pacemaker, where it handles the patient's needs in a very dynamic way without any human intervention, and the expert systems that we propose to market, where the health care provider always intervenes between the output of the computer and the action on the patient. So I believe that gives a picture of how I feel. I think that was in my written testimony also.[13]

The problems in liability—my ideas reflect that of Jack Myers. His computer science cohort, Harry Pople, has testified in another book called "The AI Business" where that specific problem was ad-

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[8] Mr. Baker revised this paragraph as follows: "Well, we have to provide a way of doing the initial validation of a knowledge base so that it does represent what's the best current state of knowledge in the country. Then, after it goes to the marketplace, we will have a continuing education problem to address to keep our systems current."

[9] Mr. Baker revised this paragraph to read, "I believe Dr. Myers' system needs to be updated about eve y two months with the new knowledge that comes in. Before that new knowledge can be incorporated into the system, it has to be examined as to how its incorporation changes the total system. It can have a ripple effect on the system's capabilities as this new knowledge is incorporated into it."

[10] Mr. Baker revised this paragraph to read, "So there's an ongoing responsibility of the community, and especially the organization marketing these things, to provide this dynamic validation activity, and, I'll repeat again, it's like a continuing education problem of the computer system and analogaus to that of the physician. So that's how I think we would base our products and assure that it operates in the best way possible."

[11] Carl W. Bruch, Ph.D., Chairman, "Report by the Task Force on Computers and Software as Medical Devices" (Washington: Food and Drug Administration, January 1982).

[12] Mr. Baker changed this paragraph to read, "My relationship with the Food and Drug Administration has been very informal. I have some contacts there. I have seen some of the reports on these matters. They generated a report in 1982 dealing with computers in medicine. It focused primarily on those systems where there is no human intervention between the computer and patient."

[13] Mr. Baker revised this paragraph to read, "I wish they had made that simple distinction in the paper they submitted for this hearing; there is a big difference between a computer embedded in a pacemaker, where it handles the patient's needs in a very dynamic way without human intervention, and the expert system that we propose to market, where the health care provider always intervenes between the output of the computer and the action on the patient. So I believe that gives a picture of how I feel about this specific problem. I think that was in my written testimony also."

dressed, and Harry Pople's picture of it and mine are not from the medical point of view or the legal point of view but what we see happening, and that is that there will be a case in time in the courts where it will be decided that it will be malpractice not to use one of these systems—for the human not to use one of these systems because of the infallibility of the memory, the extensive knowledge base that's available there. A lot of people will probably jump down my throat at that notion.[14]

I believe that concludes the overview I have.

[The prepared statement of Mr. Baker follows:]

[14] Mr. Baker changed this paragraph to read, "The problem in liability—my ideas reflect those of Jack Myers. His computer science cohort, Harry Pople, has stated in a book called "The AI Business," where the liability problem was addressed, that eventually it will be resolved in the courts. Harry Pople's picture of it and mine are not from the medical point of view or the legal point of view but from what we see happening in similar products. There will be a time in the court where a case will be decided that it will be malpractice *not* to use one of these systems. For if the human physician *does not* use one of these systems the infallibility of the system and the extensive knowledge base that's available there is *not* brought to bear on the patient's problems. A lot of people will jump down my throat at that notion."

COMMITTEE ON SCIENCE AND TECHNOLOGY

Subcommittee on Investigations and Oversight
The Use of Information Technology
and Artificial Intelligence Techniques
in the Health Care System

March 18, 1986

Introduction

My name is William Roy Baker, Jr. I am honored to have this occasion to discuss with you the present applications and policy issues in the use of medical computer systems. I am interested in an area which is the subset of artificial intelligence techniques called knowledge-based systems or "Expert Systems". I started Knowledge Research Associates in 1984 to explore the opportunities to market clinical expert systems.

1. Marketing of Clinical Expert Systems (Artificial Intelligence Software)

I spent twelve years at the National Institutes of Health managing grants dealing with the clinical applications of artificial intelligence. In 1983 it appeared to me to be the right time to move some of the research projects in this area to the marketplace. The essential ingredients of such an effort include:

Access to venture capital willing support validation of the expert system operation until a national consensus is reached,

Sensitivity to the nuances in dealing with intellectual property of clinical experts who, in turn, are concerned about the opinions of their cohorts on this new technology,

A scheme acceptable to the builders, the venture interests, and the company to validate new knowledge as it arises, incorporate it in the system, and determine the impact of the new knowledge on the system as a whole, and

Assurance to the physician customers that the use of such systems will diminish the the risk of malpractice action rather than increase the risk of such action.

2. Successes in Marketing Expert Systems.

Helena Laboratories provides as an option to its blood serum protein analyzer, an artificial intelligence expert to perform recognition of the the protein patterns generated by this test. The clinical pathologist then has the option to use the machine findings or to examine the patterns himself. The machine's expert output is used only at the discretion of the human pathologist. The major complaint I have heard from the clinical pathologists is that the machine in this system does not know enough about the patient to help the pathologist in his decision making process that follows. Compared to other clinical expert systems this is a very small one (just over 80 rules) while disease oriented systems have knowledge bases ranging from 500 to over 3000 rules.

There are other systems on the market that propose to provide expert advice in various clinical domains. Since none of them have a validated or refereed knowledge base or decision making system I have not followed their marketing. I suspect poor acceptance by physicians because their natural conservatism will require human consensus on the clinical decision process for a given disease.

3. An Example

Helena Laboratories contacted the artificial intelligence group at Rutgers University about the feasibility of introducing computer expertise into one of their laboratory systems. The Rutgers group, working with their collaborator pathologist at the Cleveland Clinic, was able to squeeze this laboratory expertise into a very small microcomputer embedded in their laboratory instrument. Because of the development of the Rutgers' technology for building expert systems and the limited size of the system, this cooperative effort produced a marketable system within twelve months of its beginning. I do not know if this expert system is a money maker for Helena Laboratories.

4. Problems Encountered

When I first left the National Institutes of Health I thought the major problem would be enlisting venture capital. After being a subject of a vignette in a weekly business magazine, ample venture capital turned up. The frustrating problem I have had in bringing clinical expert systems to market has been with academic investigators who are never able to conclude that their projects were nearly ready for commercial dissemination. The most important technical problem is that the clinical applications of expert systems represent a new and radical product. At the present moment the projects dealing with diseases do not operate with clearly defined boundaries on their domain expertise. Until machines can be taught to operate only within the intended limits of expertise, human oversight is mandatory. Substantive interpretations by the computer can be dealt with by the the physician using the system affirming that he has run the system (with its inexhaustive knowledge base) and that its outcome matches his own decision. The physician will be ultimately responsible to the patient, for it will be his decision (until the courts decide otherwise) to use the computer interpretation of the patients problem(s). I believe these notions imply intensive and extensive intellectual power that is the best national consensus represented in the computer. How this is to be done is critical to the future of expert systems dealing with human diseases.

5. Validation of Disease Expertness

The process of validating these knowledge-bases is interesting. There is available private funding to support this process, with all its uncertainties. Leaders of the projects dealing with rheumatology and high blood pressure wish to undertake system validation themselves. In fact the rheumatology project is now incorporating knowledge from Ireland and the United Kingdom and will be validating its decision making operation at sites in those countries as well as the USA. I believe these are the right steps but they could be conducted at least two to three times faster with private funds. There is ample interest among leaders in the different disease domains to conduct essential system validation with real cases at their own institutions. This community has yet to resolve the best way to handle the validation part of this new kind of process.

The technical thorn remaining is how to teach the machine its limits of knowledge and constrain its operation to remain within these limits. It is imperative that each system sold be accompanied by warnings to its users where the systems outputs should be disreguarded. The boundaries of knowledge are never static. A process for updating all the systems sold with validated new knowledge and its impact on system outcomes must be provided. The updating process is quite similar to, but cheaper than, the continuing education our human physicians undergo.

6. Role of the Food and Drug Administration (FDA)

In 1982 the FDA's Bureau of Medical Devices reported on "Computers and Software as Medical Devices." According to the Director, FDA Freedom of Information Staff this report was the only one available in 1984. Evidently no other task force had been charged at that time. My relationship to the FDA has been limited to personal contact with one member of the task force producing the above report. According to this contact no substantive gains have been made in understanding FDA's role since the report. I would like to give a brief outline of the report's recommendations:

> The FDA should:
>
> Develop guidelines for use in reviewing computer and software for its internal use..
>
> Develop guidelines for inspections and regulatory actions..
>
> Give increased attention to software development and maintenance rather than post release validation..and
>
> Monitor the field and assess problems with "computer/software" as medical devices.

The task force described what they called Computer-Assisted Medical Devices. On pages 11 and 12, they defined computer software used in medical devices as that which would certainly include expert systems along with non-human intervention systems which put the patient at highest risk.

I would recommend the FDA proceed with all speed to get a handle on the high risk devices such as computer controlled drug delivery systems and other systems not monitored by a human or not requiring human intervention in its action on the patient.

I would recommend that the FDA work with those private or public organizations validating expert systems to provide within the FDA an expertise capable of recommending FDA's role.

7. Liability Issues

I am rather sanguine about liability associated with the use of validated clinical expert systems. After a number of the systems have been sold in several medical domains, I believe we will find the same experience in the courts that users of other high technology systems have found: that failure to take advantage of the advanced capability, when that capability is available in the community, represents malpractice. This has been brought home in the DC area in dealing with CAT scanning capability available in the area not being used in one case.

Prognosis

While we think we have covered most of the bases in bringing our expert systems to the country, the attention this subcommittee is giving to the area will open up new approaches, solicit new allies and spotlight the critical barriers to offering higher quality care at lower cost.

A Profile of William R. Baker, Jr., Ph.D.

Dr. Baker rose through the ranks at Vanderbilt University from Instructor in Mechanical Engineering to Professor of Engineering and Chairman of the Department of Biomedical Engineering before moving to the NIH. He has consulted with the space industry, shoe industry, arms industry and outdoor sign industry on problems involving dynamic systems analysis as well health care services enterprises.

Dr. W.R. Baker, a 12 year veteran of the National Institutes of Health (NIH), left NIH in 1984 to bridge the gap between academia and the marketplace in medical expert systems. Dr. Baker has a unique position in the technology of computer expert systems. He was instrumental in motivating the academic community to move to clinical applications following the successful demonstration of DENDRAL, the first real artificial intelligence system. During 1972-73 he shaped management arrangements that triggered the emergence of a national community identified as Artificial Intelligence in Medicine (AIM). At that time these investigators did not have access to the computing capacity (blocks of memory) essential to fruitful progress of their research. With Drs. Edward Fiegenbaum and Joshua Lederberg at Stanford University, a computing resource was built at that provided the nation's investigators access to the shared capacity needed for AI research and intellectual connections to facilitate their work on knowledge based systems in biomedicine. AIM has grown to include approximately 250 computer scientists, 100 physicians, and 250 students. The level of support is about 5 million dollars per year covering salary , computer network, and computer capacity. The total NIH investment over the 12 years of AIM through Dr. Baker's program exceeded 60 million dollars.

Only two of the AIM projects have been commercially diffused. These are laboratory applications in molecular genetics and protein serum patterns recognition. However, none of the clinical applications are commercially available. There are good reasons for this. The clinical projects are much more complex and validation by other institutions is expensive and holds little academic reward. Dr. Baker has embarked on bringing these systems to market through his company, Knowledge Research Associates.

While Dr. Baker is formally trained as an engineer, his interest beyond just using the computer as a tool came about in the early seventies. Designers of systems at that time designed the systems to be used by their own kind and naive users were not welcome on these systems. The environments in which these systems ran were frequently changed thereby voiding much of the investment in programming. It was a juvenile game in which the ADP specialist was the only player. Meanwhile, MDs doing research had accentuated the need for mechanization of data management and analysis. At that time even clinical investigators who could program would not invest their time in developing a system likely to have a short life time because the computer managers changed the operating system. Dr. Baker initiated a the CLINFO(R) project at NIH dedicated to the task of data management and analysis for clinical investigation. The project was started in 1972, the initial system built in 1975 and three prototypes installed in 1976-77. The system looks like today's third generation spreadsheet, graphics, and data base systems such as Lotus 123 or SuperCalc 3. In 1977, CLINFO (R) was deemed a success and the process of commercial diffusion of this government product was initiated. At present over 60 installations have been made by Bolt Beranek and Newman, the NIH selected purveyor of the CLINFO (R) system. Dr. Baker provided the product with protection by applying for and receiving the trademark, CLINFO (R). The mark is assigned to the DHHS. Today the CLINFO (R) system has about 800 MD users throughout the land today at over 60 installations.

Dr. Baker left The National Institutes of Health in 1984 to explore the opportunites for marketing the artificial intelligence systems his NIH program had supported. The most pressing problem then was venture capital for building the company. A vignette of Dr. Baker's effort published in the summer of 1984 in a business weekly virtually eliminated capitalization issues for his organization. The remaining obstacle is the release of expert systems by the physician builders in academia.

Dr. Baker has recently been asked to serve as the Washington, D.C. area correspondent for Argus Computing Inc., a Kansas City, MO company, whose computer operations generate about $10,000,000 per year. He acts as their agent in medical computing for the DC area.

Mr. VOLKMER. Thank you very much, Mr. Baker.

I have a few questions.

I first want to thank all of you for being here today, and I'd like to start off with a question, Dr. Myers, that has arisen in an article in the January 1986 issue of Technology Review.[14a]

Hubert and Stanley Dreyfus, of the University of California at Berkeley, criticized artificial intelligence research like yours on the basis that human experts do not use rule-based logic in order to solve problems and do not process information serially. They claim that no computer system will ever be able to master the holistic, image-based method of information processing they advocate as the model for human thought. How would you respond to their arguments? Have you reviewed the article?

Dr. MYERS. No, I have not seen it, but I have heard this.

Mr. VOLKMER. So you're a little familiar with it.

Dr. MYERS. Right.

I would agree that it's going to be very difficult, if not impossible, for a computer program to mimic the highest of our human intellectual activities. I have some mistrust of computers, for example, describing new diseases, whereas you and I, after we see a certain number of cases of Legionnaire's disease say, "Ah, that's something new," and go ahead and describe it. Others would believe that computers could do this.

But let me tell you what we mean in our program by artificial intelligence. That's a funny term, to begin with, as I'm sure you realize. But what we did in our team, since I've had a lot of experience in making diagnoses, I sat down with the computer scientists and with the aid of a couple of younger physicians and analyzed dozens and dozens of cases until they could see what the human logic in medical diagnosis was like. Then they wrote computer programs to mimic this. It's a little different from the point of view given in that article.

Now there are other systems that are heavily rule-based. We have rules in our system but not nearly so heavily as some of Dr. Shortliffe's [15] programs, for example, which are probably referred to in the article.

I think one has to realize then that we're making our best effort in a number of directions—I'm talking about people working in the field now—are making their best effort in a number of directions to build these inference agents—engines—inference engines to simulate the human reasoning and logic in problem solving, not just in medicine alone but in other fields, and I think that we've made good in-roads. I'm not worried about this criticism.

Mr. VOLKMER. Now, basically, is the Caduceus organized, as far as the computer-based knowledge, relative to the types of diseases, et cetera, or is it based on—organized on functions of the parts of the body and how they react? What is the database programming basically organized on? I'm just trying to——

[14a] Hubert and Stanley Dreyfus, "Why Computers May Never Think Like People," Technology Review, January 1986, pp. 42-61.

[15] Dr. Edward Shortliffe is assistant professor of Medicine and Computer Science at Stanford University (Palo Alto, CA) and is one of the developers of the MYCIN expert system.

Dr. MYERS. That's a good question, and this is another thing that has evolved, in a sense. But the great part of our knowledge base is disease-oriented. What we do is, we take one of the 750 or so diseases in the broad field of internal medicine, and a group studies it in depth, in the library, with medical experts—wherever you can get reliable information—and then we draw up a list of all the manifestations of that disease; that averages about 150 per disease; and then we put some semi-quantitative figures on each one of these, and we call that the profile of the disease.

So far we've used about 4,100 different manifestations of disease, the way diseases in general can show themselves in a human being—fever, or substernal chest pain, and so on. The computer, once it gets the profile of the disease, can automatically invert that. So if you want to look up, well, what diseases in this whole list of 600 cause fever, you can get that out in about 15 seconds.

We also have to build in all the interconnections among diseases, because in medical diagnosis, like most problem solving, it's only logical to try, if you have a complex problem, to make a number of conclusions that are inter-related rather than independent; that's just good, sound logic; and for the computer to do that, it has to know, of course, all of the interconnections among these many diseases.

That, in a nutshell, is the way the knowledge base is built.

Mr. VOLKMER. Now, you indicate that your work in expert systems grew out of problems diagnosticians face due to their limited ability to remember everything in the growing body of medical knowledge and the brains and intelligence—human brain's apparent inability to imultaneously consider more than 7 or 9, or possibly even 10, at the most, alternatives. In developing your system, have you learned anything that would improve the process of diagnosis itself?

Dr. MYERS. Only a very broad——

Mr. VOLKMER. On a human level, by the doctor himself.

Dr. MYERS. Well, I look in my own mirror to answer your question. Only in a modest way.

I find that as I teach medical students now on ward rounds that my behavior is a little different than it was before, and I'm much more ready to say, "Look, we need some information here; let's go to the terminal and get it, and then continue this discussion." But I don't think it's basically changed how one reasons.

Mr. VOLKMER. Now as I understand it, Caduceus is basically nothing more than a textbook. Is it an electronic textbook?

Dr. MYERS. The knowledge base is a textbook, but I think I can say it contains more information at this juncture than any textbook that you would take off the shelf.

Mr. VOLKMER. I agree with that, but I mean it could be—you could take that, if you want to, and print it out, and the doctor could look it up in a printed textbook——

Dr. MYERS. Yes, absolutely.

Mr. VOLKMER [continuing]. Which would be no different than getting it as a printed form on a display.

Dr. MYERS. That's right, and we've had a few publishing companies provide overtures in that connection. We haven't done anything about it.

Mr. VOLKMER. But does it not also make recommendations to the physician?

Dr. MYERS. That's the diagnostic component. That's the second component. Yes, it does.

Mr. VOLKMER. But these are not, as far as any medical physician is concerned, a final determination; he still has to determine whether or not he wishes to follow that recommendation.

Dr. MYERS. That's our intent, clearly. Now I think you probably know that in certain walks of American life, part of the public at least believes more in machines than they do in other human beings. There's always a danger, you see, that somebody will just say, "Well, that's the answer; let's go ahead." We do not intend that. That is not proper, in my opinion, at all. These are advisory programs.

Mr. VOLKMER. That's what really got me to the following question. Where do we go from here if we get to the point where the physician decides that, "Hey, that machine, Caduceus, was right the first time; the second time; the third time; from now on, I'm just going to do whatever it says?" Is there any possibility that we get to that point where the doctor just decides, "let's leave it up to the machine?"

Dr. MYERS. Well, I think if we had a perfect machine we'd probably get to that point, but, you know, the program we're talking about is clearly not perfect. I wouldn't make any claim that it is.

You see, medical information is, as you well know, not complete, and part of the information we have, unfortunately, is incorrect.

I always like to quote William Osler when he was at the University of Pennsylvania, before he became chairman of medicine at Johns Hopkins. He was giving the graduation address to the seniors at the University of Pennsylvania—this was in the 1880's—and he gave his usual eloquent address and then concluded by saying, "Ladies and gentlemen, I'm very sorry to tell you that half of what I've taught you while you've been medical students is false, but the real problem is, I don't know which half it is."

I think we're better than 50–50 today, but, you know, we're not 100 percent by any means.

Mr. VOLKMER. Could you use Caduceus? Let's say that I'm the physician, and I have Caduceus, and I use it, and I plug in all the symptoms, et cetera, and it comes back with a recommendation, and I follow that recommendation, and the patient really isn't getting well. Could you use Caduceus to put it as a kind of peer review to see if I've done the right thing, sort of plug into what I've done and see what Caduceus comes back with and says, "No, you shouldn't have done that; you should have done something else," in light of the present circumstances of the patient?

Dr. MYERS. We actually haven't put that to the test, but I see no reason why it could not be used for quality evaluation.

Mr. VOLKMER. Then the last question is, let's assume that the physician could and eventually we'd get to that point. Now the patient has passed away, and I'm the widower, and I say, "Hey, the doctor didn't do right." Can the lawyer then plug into Caduceus and say, "Did he do right, or didn't he do right?"—my malpractice lawyer now.

Dr. MYERS. Well, one can check out any diagnostic problem with the system and see, you know, how well does it work.

The other thing I should make clear, in using the system as we envision it in the long run—and I hope you understand, we're not ready that this be released to the general medical public at this point; it's incomplete. The program is used in stages.

The physician, once he recognizes a tough problem, will put in what data he has, get back an analysis; probably all he'll get at that point is a differential diagnosis, a list of the leading contenders. Then as he gets more information, say, 2 or 3 days later; he comes back and adds that to the case—he doesn't have to start from scratch now but adds it to the case—gets another analysis, and so on, in various stages; and at each point the computer, by questioning the physician, will indicate to him what data should be obtained to try to solve this tough problem. So it guides the patient's workup from day one on, if one uses the system in that way.

Mr. VOLKMER. Fine.

Dr. MYERS. Not a one-shot deal, in other words.

Mr. VOLKMER. My last question—and I may have additional time constraints; I'd like to go on all morning, but we've got another panel, and I want to ask questions of the other members of this panel, but does Caduceus ever provide to the physician, I wouldn't say an ambiguous answer, but alternatives as to solutions that may be—you know, come up, depending on the input of the systems, et cetera—say, "It could be this or this?" Does that happen, or could that happen?

Dr. MYERS. Absolutely. You see, it's very conservatively built at the present time, and in order to conclude a diagnosis it has to have quite strong evidence for that, very strong evidence. If it does not, it will tell the physician what the two to four leading contenders are in order but doesn't solve the problem.

So quite frequently, particularly when information is not thorough, it will defer a diagnosis or tell you, "I can't resolve this problem." But in the course of getting that evaluation, the machine will indicate, as I said before, what other information could be useful, so you might come to a conclusion, and the physician then, according to his judgment, will get that extra x ray or laboratory test, and, as I've observed the way the system asks for that information, it's quite cost effective. It doesn't take a shotgun approach in any sense.

Mr. VOLKMER. Is the machine purely a diagnostic tool?

Dr. MYERS. At the present time it is.

Mr. VOLKMER. So it's not a treatment tool at all.

Dr. MYERS. No. We would like to add treatment, you know, but I hope you realize, we've taken on a very tough task.

Mr. VOLKMER. I understand that. I think you've done well with what you've done to get that far. As you've mentioned, with medical knowledge continuing to grow and change every day, I think even keeping it up to date would be a monumental task.

Dr. MYERS. It is.

Mr. VOLKMER. Dr. Gardner, in reviewing your written statement, I find some things, what with the growth of the HELP system, quite intriguing. You mention in there the trauma victim, et cetera, and how the HELP system would affect that person.

Let me ask you, let's say the person's under a basic treatment and there's a change in that trauma victim's, let's say, blood pressure, and the fever's going up, or something like that, and the system then makes a recommendation—does it not?—as to whether additional drugs or additional type of treatment is necessary. Would the machine actually make those, based on a monitoring of the person's condition?

Dr. GARDNER. The machine could.

In general, what we've done is—the machine makes interpretations, provides alerts, and in some cases—in a few cases, will make therapeutic suggestions.

Let me give you an example of a therapeutic suggestion. Let's say a patient has a fever, the physician has done a culture on it, sent it to the laboratory; that takes 24 or 48 hours. The results now come back, and let's say the patient's being treated with—the physician says, "Well, I know he's got a fever; he's got an infection we're going to treat with penicillin."

Let's say the result comes back and there's a sensitivity test done that says, "Hey, the bug this patient has isn't sensitive to penicillin," and the computer will then say, "Hey, discontinue penicillin, or at least give another drug that the bug is sensitive to," and in that way we do make some therapeutic suggestions, but in general it's interpretation of the data and providing alert to life-threatening situations that the computer provides us.

Mr. VOLKMER. That data—let's say, like you say, the lab work's done; at the lab, they plug it directly into the computer. Is that correct?

Dr. GARDNER. Yes. The laboratory——

Mr. VOLKMER. Then the computer makes an analysis by itself.

Dr. GARDNER. Yes.

Mr. VOLKMER. Then it puts it out. Does it put it out—this person is, let's say, not in the ICU area but maybe down on a regular floor. Would it put it into where the nurses' supervisor—who is going to get that information at that time? Where is it going to go? Or is this only on the ICU's?

Dr. GARDNER. No. This is hospital wide,[16] and if we have drug interactions—for instance, someone allergic to aspirin and they give a drug that has aspirin in it; the pharmacist picks that up as they enter the drug into the system, and it comes back and says, "Don't dispense that drug because it has aspirin."

In the case of the microbiological results, that's probably the nurse on the floor, or we have the system feeding back to our infectious disease people, and we can also feed back to individual physicians.

So the key is to find the person who is the decisionmaker. Physicians aren't always in the hospital, they aren't always available, and so we've really gone to nurses and pharmacists and other people who are readily available so we can have them as the action point.

Mr. VOLKMER. That's my next question—the thing that I wouldn't say "bugs" me, but bothers me a little bit. Normally, is it

[16] Dr. Gardner revised this to read, "This is a hospital-wide system . . .,"

not true that at least medications, what we call prescription medications, normally have to be prescribed by a physician?

Dr. GARDNER. Yes.

Mr. VOLKMER. What I see can occur is that the machine could make the interpretation, along with the pharmacist, and that could go to the nurse on duty, and since there's no physician, that the nurse could then make a change, along with the pharmacist who sent the pills up, and it goes to the patient. Is that correct?

Dr. GARDNER. No. Physicians still have to make the change, and in fact with our pharmacy we have physicians complying over 90 percent of the time; 10 percent of the time they say, "Hey, we want to continue to give a certain drug." No drugs are changed by pharmacists or a nurse without a physician's orders.

Mr. VOLKMER. In other words, even recommended by the HELP system, it would still have to be approved by a physician.

Dr. GARDNER. That's correct.

Mr. VOLKMER. OK. Now in validating the decisionmaking software in your system, you're testing it against the information programmed into the database.

Dr. GARDNER. That's correct.

Mr. VOLKMER. Have you ever noted a case where the information available to the system was not complete enough to allow it to properly evaluate risk or a patient's condition—where it came back and said, "Hey, I can't answer that one?"

Dr. GARDNER. Oh, there are a lot of times. In fact, it won't even make decisions in those cases, and in some cases we—say if we needed five pieces of data and we have four; the system will come back and say, "Hey, if you'd please give us this piece of information, we could help you with an important decision."

Mr. VOLKMER. All right.

Dr. GARDNER. So we have what we call an ask mode, so it will ask for data that's missing.

Mr. VOLKMER. Or it will verify the fact that it cannot give it even with the data, if it doesn't have the database.

Dr. GARDNER. If it doesn't have the data, it won't make the decision.

Mr. VOLKMER. Right.

How often would you [illegible] that the knowledge bases in the systems are updated in your system?

Dr. GARDNER. Well, if they're new, they're updated on a monthly basis or more often. If they're more static, like our blood gas and pharmacy things,[17] you know, perhaps every 3 to 6 months, just fine tuning.

Mr. VOLKMER. Now I suppose this one is basic, and I'm sure you address the problem. The system does monitor patients in the ICU; we've seen that—right?

Dr. GARDNER. Yes.

Mr. VOLKMER. What steps have you taken to address problems of computer failure or power interruption?

Dr. GARDNER. That's a nasty problem for us in the hospital. We have power failures more often than most folks because they have

[17] Dr. Gardner charged "things" to "programs."

diesel generators, and they'd like to try those out, so when there is a power failure they can survive it, and so we have automatically, every month, two power failures when they go on the diesel generator and when they come off.

To resolve those problems, we've put battery backup supplies in our intensive care units, we have a flywheel system in our other computer systems, and right now we're using Tandem™ computer systems which have at least two processors—we happen to have six at the moment—and those systems are nonstop systems much like are used in the automatic teller systems that banks use; if one processor fails, the other one picks up the load and carries it on.

So reliability of the 99.6/99.9 [percent] range is required if you're going to do that in hospital.

Mr. VOLKMER. I figured it was a basic that you had to address it, and you have.

Dr. GARDNER. Yes.

Mr. VOLKMER. You have mentioned in your oral presentation, I believe, the figure—was it $250,000 savings through efficiencies, the use of the HELP system to the hospital?

Dr. GARDNER. That's just in respiratory therapy.

Mr. VOLKMER. That's just in respiratory therapy. Could you give us—if not today—an estimate, not just off the cuff but something reliable, as to the savings totally to the hospital by the use of the HELP system? You don't have to do it today, if you can't do it right now, but if you would do it in writing, I'd appreciate it.

Dr. GARDNER. OK; I'll do that. That's a tough one.

Mr. VOLKMER. Fine. You know, if it can be done without too much difficulty, or get us some rough estimate of what you consider.

[The information follows:]

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August 22, 1986

Harold L. Volkmer, Chairman
Subcommittee on Investigation and Oversights
House of Representative Committee on
Science and Technology
822 House Annex One
Washington, D.C. 20515-6307

Dear Mr. Volkmer:

Enclosed please find some additional material I promised to send on cost effectiveness and related issues. Also a recent publication on JAMA on our Infectious Disease Monitoring System.

Sincerely,

Reed M. Gardner

Reed M. Gardner, Ph.D.

Enclosure

May 7, 1986

IMPACT OF A CLINICAL INFORMATION SYSTEM ON HOSPITAL COSTS

Reed M. Gardner PhD, R. Scott Evans PhD,

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R. Scott Evans is a post doctorate fellow at the LDS Hospital. He has been a pioneer in the development of automated decision analysis of infectious disease data. He is currently an investigator on a Public Health Services Grant to assess the value of computerized infectious disease monitoring.

Robert D. Andrews is a systems analyst at the Salt Lake City Veterans Administration Hospital Region 5 Information Systems Center located in Salt Lake City. He has done extensive development and evaluation work in applying computers to medicine.

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IMPACT OF A CLINICAL INFORMATION SYSTEM ON HOSPITAL COSTS

Reed M. Gardner PhD, R. Scott Evans PhD,

Robert D. Andrews MS, MT(ASCP)

Concern over the rising costs of medical care has been expressed frequently by patients, legislators, and members of the health care community. The public expects "perfection" when it comes to medical care delivery. When an individual patient is considered the expectation is that "maximum" care will be given. To help prove that these expectations are being met there is a growing demand for documentation of the clinical care process as well as proof of procedures being done. A major part of the cost of the care provided in hospitals is for personnel (57% at LDS Hospital affiliated with the University of Utah) and a major part of these expenses are for personnel who provide direct patient care (Nursing 37%, Surgery 7%, Laboratory 5%, Respiratory Care 4%, and X-Ray 4%). Anything which will make the care process more efficient will be welcomed.

At the same time that there is a need for improved efficiency in health care delivery, medical knowledge, new drugs, and new medical procedures abound. The decreasing cost of computers with their increasing capability present an attractive solution to many of the hospital problems of being efficient yet at the same time delivering "state of the art" care. It has been observed that many errors in medicine appear to be due to errors associated with simple clinical events which the computer might help avoid. Also there is evidence that clinically relevant

medical knowledge is frequently not applied either because of ignorance and/or the inability to process all the patient data. Therefore, with the cost of computers dropping and the need to perform simple repetitive tasks, which the computer is capable of doing, we find ourselves in an ideal position to have the computer help us with the "clinical" tasks of medicine and at the same time help us with the task of efficient documentation.

Evaluation of the cost effectiveness of any process in the health care field is complex. As a consequence, studies in this field, especially as they relate to the use of computers, are limited and open to challenge. Only recently have computers been used to enhance the "clinical" practice of medicine. We present four example studies where benefits have been shown using the HELP computer system at LDS Hospital in Salt Lake City, Utah (Pryor et al 1983).

Pharmacy Alerting

As prescribed drugs are entered into the HELP system by clinical pharmacists on nursing divisions, a "knowledge base" of drug-drug interactions, drug-laboratory contraindications, and allergies, screen patient data for potential complications (Hulse et al 1976). If the drug is contraindicated for any reason the clinical pharmacist is notified before the drug is dispensed. Compliance of physicians with these alerts occurs more than 90% of the time. After observing the high compliance rate and the positive attitude of our physician staff we began to explore

methods of evaluating benefit-to-cost ratio of our system. Cost data was readily available because each clinical module is only implemented after initiation of a charge for service. Statistics were logged on the number of prescriptions and number of alerts that were generated by the computer system. However, evaluation of the benefit of the pharmacy alerts was more difficult. The value of each drug alert was highly variable depending on whether or not the drug reaction would actually occur and what the degree of severity would be. To make the benefit assessment quantitative, expert opinions on the value of each pharmacy alert were obtained independently from five clinical practicing pharmacists.

During a two-year period over 53,000 patients were monitored for more than 246,000 patient days. Less than 4% of the patients had pharmacy alerts and less than 0.7% of the drugs ordered resulted in alerts. The current charge made to patients for the pharmacy alert service is 35 cents per patient day, just over $86,000 for the two year period. The estimated benefit from the experts was more than $339,000. Therefore, the benefit-to-cost ratio was a highly favorable 3.94 to 1.

Laboratory Alerts

A second alerting system was established after experience with the pharmacy alerting system produced such encouraging results. As laboratory data was sent to the HELP system from the clinical laboratory, a "data driven" knowledge base was

automatically applied. If the patient data indicated a "life threatening" condition an alert was generated. A randomized design was set up to help evaluate the effectiveness of these alerts. When an alert occurred on a study patient, a nurse clinician promptly gave the information to the patient's physician. Control patients' physicians were left to obtain the information on their own through computer or by reviewing the patient chart, and were given no computer prompts about the alert condition. All patients were followed up by nurse clinicians using structured protocols based on action-oriented criteria.

There were several categories of alerts where physicians' treatment patterns were changed. The incidence of life threatening alerts based only on laboratory data was small. Only about 4% of the patients, outside the intensive care unit generated alerts and approximately half of these were treated correctly and promptly. Even though the number of alerts was small there was still a positive effect on physician behavior. Physicians liked the "realtime" alerts because they were made available to them at a time when it was most effective for them to modify their treatment decisions.

Microbiology Monitoring

The costs of inappropriate antibiotic therapy, hospital-acquired infections, and continuous surveillance by infectious disease personnel contribute to the expenses incurred by patients. At present, antibiotics as a group are one of the most

frequently prescribed drugs and represent more than 35% of drug costs (Hendeles 1976). Thirty to forty percent of all hospitalized patients receive one or more antibiotics during their hospital stay; however, up to two-thirds of these patients may have no evidence of infection (Maki and Schuna 1978).

Antibiotic therapy is usually started before the culture results are available and physicians most choose a broad-spectrum antibiotic. Broad-spectrum antibiotics cover a wider range of possible pathogens but are often more expensive. The final susceptibility results may demonstrate that a less expensive antibiotic can be used or the culture may be negative indicating that no drug is required. In choosing therapy, the most effective and most cost effective antibiotics may be passed over. In addition, with new agents being introduced at an unprecedented rate, it is increasingly difficult for physicians to keep abreast of important pharmacological developments and costs (Avorn and Soumerai 1983).

Antibiotic prophylaxis is used in surgery patients who are without infection, with the objective of reducing subsequent postoperative infections. Studies show antibiotic prophylaxis should be limited to only high risk patients, or to those for whom the development of an infection might have a catastrophic result (Veterans Administration 1977). Prophylactic drugs should usually be stopped within 48 hours, since continuing prophylaxis increases the risk of drug toxicity and bacterial superinfection, and does not reduce the incidence of subsequent infection

(Medical Letter 1979).

During February and March 1979, the Utah Professional Standards Review Organization conducted a study of prophylactic antibiotic use in twenty-one Utah hospitals (Britt et al 1981). The study included 2,782 patients of which 1,163 (46%) received antibiotic prophylaxis. Prophylactic antibiotics were used a total of 4,753 days and according to this study 3,831 days (81%) were inappropriate. At the rate of $50.00 a day (1979 prices) this practice added approximately $190,000 to the patients' bills during a two month period. The identification of patients receiving inappropriate prophylactic antibiotics required additional time, manpower and cost.

Emori et al (1980) found that infection control practitioners (ICP's) in large hospitals (> 300 beds) spent an average of 36 hours each week on nosocomial (hospital acquired) infection surveillance. Nosocomial infections represent an important endemic problem affecting 3% to 8% of hospitalized patients -- this represents more than 2 million infections annually in the U.S.. Studies have shown that the typical nosocomial infection prolongs hospitalization 4 to 10 days and increases hospitalization charges $600 to $700 (1979 prices), thereby increasing the patient's bill by about 15% (Haley et al 1981).

Patient microbiology data were added to the HELP system by interfacing the clinical laboratory computer system. With the aid of experts in infectious disease, a knowledge base was

developed that identified: 1) nosocomial infections, 2) patients not receiving antibiotics to which potential pathogens are sensitive, 3) patients who could be receiving less expensive antibiotics, 4) patients on prophylactic antibiotics longer than necessary (Evans et al 1985, 1986).

A two months study was conducted where the nosocomial infections identified by the computer were compared with the nosocomial infections found by the ICP's. Patients identified by either method had their medical charts reviewed by infectious disease physicians to verify the infections. During the same two month period the patients identified by the computer who could have received a less expensive antibiotic, had their medical charts reviewed by the physicians. The physicians decided whether the patient needed an antibiotic for a specific culture and also if the less expensive antibiotic recommended by the computer was appropriate.

The computer identified significantly more patients with nosocomial infections ($p < 0.002$) and total nosocomial infections ($p<0.03$) than the ICP's. During the two month study the ICP's spent a total of 138 hours doing nosocomial infection surveillance and analysis. Their time was spent examining microbiology laboratory summary results, checking nursing notes, and "Kardexes"; checking admit dates, discharge dates, surgeries, following up on patients in isolation, and selecting charts for retrospective review. The ICP's spent 8 hours during the two month study analyzing the data and making a summary chart. It

took 8.6 hours to take the pertinent data from the computer alert and make a summary chart for the two month study. Thus the analysis time was similar for both methods. However, the computer could have saved 130 person-hours in surveillance while at the same time identifying more infections.

Of the 155 patients found to have infections, 54 (35%) had a nosocomial infection marked on the facesheet of their chart and 101 (65%) did not. Reevaluation of these 101 charts showed that several would have received a higher DRG grouping if the medical records department had known about the infection and the hospital would have received an additional $18,000 for the year.

There were 39 computer alerts stating that although the patient was receiving an appropriate antibiotic, he/she could have been receiving a less expensive antibiotic. The physicians decided that 31 (80%) of these alerts were correct and the patient could have received the computer recommended antibiotic.

For 23 days during a six-week period all patients who were initially given a cephalosporin for the first time had their charts checked by a clinical pharmacist to see if the drug was for therapy or prophylaxis. The patients receiving prophylactic cephalosporins were then followed to see if the drug was discontinued within 48 hours. The patients who received the cephalosporins longer than necessary were compared with the patients who were identified by the computer as being on prophylactic cephalosporins more than 48 hours.

Of the 506 patients receiving cephalosporins for the first

time, 440 (87%) were receiving the cephalosporins for prophylaxis. Of the 440, 89 (20%) were discharged before 48 hours, 166 (38%) had their cephalosporins stopped before 48 hours while 185 (42%) did not. Of the 185 patients receiving the cephalosporins longer than 48 hours, 156 (35% of the 440) did not have any evidence of infection or a microbiology test ordered or waiting results. The computer sensitivity for locating these patients was 100%, and specificity was also 100%, i.e., no patient was falsely identified.

The ICP's spent 138 hours during the study (17 hours a week) on infection surveillance and analysis. This time would likely have been a great deal more at other hospitals since few hospitals have the computer review capabilities present at the LDS Hospital. Emori et al (1980) found that ICP's in large hospitals (> 300 beds) spent an average of 36 hours each week on surveillance. Checking the patients surgery data, X-ray data, previous admission dates and other culture reports was done by the ICP's at LDS Hospital utilizing existing computer programs on a terminal. The data for all suspected infection patients could be performed at one location, thus making it unnecessary to check these patient's charts. The computer notifies the infectious disease staff of patients with possible nosocomial infections within 24 hours of positive culture data. Thus, using the computer alerts the ICP's can check the patient's chart while the patient is still in the hospital, have proper treatment started, and document the infection on the chart. The prompt

identification can also benefit the patient, prevent or more promptly identify hospital epidemics, protect hospital personnel from potentially contagious diseases and help administrative services such as medical records and patient billing in recognizing nosocomial infections.

Penicillins comprised 77% of the correct recommendations by the computer. Seventy-five percent of the time when a penicillin was recommended as a less expensive antibiotic the patient was on a cephalosporin. The average cost of the penicillins given IV is $10.00 per gram whereas the average cost of the 4 most commonly used cephalosporins given IV is $17.00 per gram. If the drug is given 3 times a day for 7 days that would be a difference of $147.00 per infection. Based on the 24 cases found during the 2 month surveillance period you would expect to find 144 during a year resulting in a savings of over $21,000 per year.

During a 23 day period, 156 patients received prophylactic cephalosporins longer than necessary. The additional cost of these antibiotics given IV in the hospital is over $50.00 a day. Thus if these patients received a cephalosporin for only 1 day longer than the 48 hours, an extra $6,650 was spent on unnecessary antibiotics. For the entire year that would be an extra $115,000 just for antibiotics. However, Shapiro et al (1979) found that the duration of prophylactic antibiotic use was correlated with duration of hospital stay.

Computer surveillance is now the basis for infection surveillance at LDS Hospital. The study showed that the computer

can identify: 1) patients with nosocomial infections more quickly, more efficiently, and at less cost than the manual methods, 2) patients who could be on less expensive antibiotics, and 3) patients who are receiving prophylactic antibiotics longer than necessary. The key to reducing the cost of these antibiotics, however, is in making sure that the computer alerted patients are followed up responsibly.

Respiratory Care

Use of the computer for documenting Respiratory Care (RC) procedures is an example of how clinical information can be used for cost benefit. Instead of writing results of RC procedures in the patient's chart, therapists enter the clinical information into a computer terminal at the nursing station. The clinical information can then be used for not only reporting, but also for billing, management, and monitoring patient care (Andrews et al 1985).

Results of surveys taken before and after implementing computer charting showed that therapists preferred using the computer over manual charting. Before computer charting, 17 of 37 (46%) felt that computer charting would make their job easier, compared to 29 of 38 (76%) after using computer charting. Table 1 shows therapists felt the computer was an improvement.

Table 1. Therapists' evaluation of computer charting compared to manual charting (% of responses of 48 therapists)

	Better	Same	Worse
Time spent	59	33	8
Ease of entry	65	25	10
Ease of review	52	17	31
Accuracy	54	27	19
Productivity	77	19	4

Charting RC procedures on the computer streamlined the processing of information. Writing RC procedures results in the patient's chart has been eliminated; instead the information is entered into the computer. The results can be reviewed from any nursing division computer terminal and printouts can be easily obtained if desired. When a patient is discharged, a permanent record of all RC documentation is printed and placed in the patient's chart.

Manual charting required therapists to document billing charges on separate forms. These forms were processed by the department secretary and taken, a day or two later, to the billing department where a clerk would enter these charges into the computer. Computer charting eliminated these steps. A therapist simply charts the clinical information into the computer, the billing process is automatic and transparent.

Since billing is automatically extracted from the clinical documentation, there is complete assurance that documented

procedures are billed. This assurance is important when third-party reimbursement is dependent on the documentation of the care performed. The accuracy of the clinical charting determines the accuracy of the patient's bill.

Computer charting also gives the therapist another incentive for accurate documentation. A daily management report provides verification of all procedures that have been documented by each therapist. Supervisors can quickly ascertain that all procedures assigned have been documented. The productivity of each therapists can be accounted for and used as an objective part of the therapist's performance appraisal. The management report also provides RC department statistics of performed procedures and lists documentation of missed treatments. This information is helpful in justifying staffing requirements.

Inconsistencies and duplication of charting are easily identified using the computer. While most mistakes or uncharted procedures can be found using the management report, other, less obvious mistakes, can be searched for using the computer. Inconsistencies such as over-charges on hourly care can be checked so that a patient is not charged for more than 24 hours of therapy in a single day.

Computerized charting is also used to check that proper care is being given. Patients that are on long-term oxygen therapy without having a blood gas test performed are reported so that a therapist may assess the need for oxygen and notify the physician. Medical necessities for oxygen utilization can

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therefore be automatically monitored.

The productivity of the Respiratory Care Department is a calculation of work units done and employee hours worked. The first 3 months of 1984 (before computer charting) showed a productivity of 87.8% (the average productivity of 1983 was 89%); after implementing the computer (March thru December 1984) the productivity has averaged 106.4% (See Figure 1). The increase in productivity of 18.6% represents a savings of $220,375 per year.

(Insert Figure 1 here)

Conclusion

The above examples show how the computer can improve the quality as well as the efficiency of hospital care. From the observations made with the alerting programs we have found that:

1. The number of alerts (potential errors) is less than projected. (Medicine is practiced better that the studies suggest, although still not perfect).
2. Error rates are often small enough that human reviewers are not accurate at detecting them nor are humans cost effective at performing such tasks.
3. Many potential errors can be detected and prevented.
4. Physicians are responsive to the alerts and make changes in their treatment. Physicians also appreciate receiving the "alert" at a time when they can modify and optimize therapy.

It is only a matter of time before most data logging procedures done in hospitals will be more cost effective using computer methods. With the expected increase in efficiency will also come better records and better data to be used by medical decision-making algorithms.

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Legend

Figure 1: Plot of productivity of therapist in Respiratory Care Department before and after implementation of computer charting.

Mr. VOLKMER. You also, I guess, since you're a proponent of it, feel that it does provide for better medical care for patients.

Dr. GARDNER. We've done several evaluations that point that out, and the quality of the records are better; the people who use it are positive about it; we give feedback to physicians; they're very supportive; and I get, you know, two or three times a year one of my pulmonary colleagues—pulmonary docs—comes by and say, "Hey, you saved my skin again today on a problem," and I would classify him as one of the very best physicians I know. He occasionally makes a mistake, and we pick up on it, and he appreciates us finding it before the drug or whatever is given.

Mr. VOLKMER. Do you ever lose any patient's record on the HELP system?

Dr. GARDNER. Again, as part of our reliability, we have two copies of everything—two disk copies—and we make tape backups.

Ever is a long time, and I'd say yes, we've lost data, but it's uncommon, and more commonly we have our medical records department call and say, "Hey, we've lost these reports; could you regenerate us one?" We go back to tapes or disks and retrieve that data for them. So we lose less than the paper record.

Mr. VOLKMER. Do you know that during a treatment period where data for a patient has been lost and therefore the treatment has to be, you know, put in limbo for a while until you retrieve it? Has that ever occurred?

Dr. GARDNER. I'm not aware of any cases.

Mr. VOLKMER. All right. You mention in your oral presentation the Food and Drug Administration and your position on that. Has it, do you know, expressed any interest in your system? Have you had anybody from the Food and Drug Administration visit you and go over it with you or your staff?

Dr. GARDNER. No.

Mr. VOLKMER. Have you had any communications at all from them?

Dr. GARDNER. Yes, we have. In fact, at the Association for the Advancement of Medical Instrumentation meeting last week in Chicago, the chairman of the session, who was from the Food and Drug Administration, invited several of us here today to make presentations on medical expert systems. So there has been some interaction in that way, yes.

Mr. VOLKMER. But you haven't had any—that you know of, at least—interest by them to regulate your system?

Dr. GARDNER. No.

Mr. VOLKMER. And, as I understand it, with the security methods that you've employed, you're not too concerned about unauthorized persons getting hold of patients' records with these security devices that you presently have for those doctors that can call in and use it?

Dr. GARDNER. The call-in system is quite secure. The security within the hospital probably could be better. We wanted to make it very secure, but our physicians said, "You've got to make it easy for us to use, or it won't be a helpful tool." We could probably tighten that up and probably should. Physical security of the terminal is our primary security measure.

Mr. VOLKMER. In reviewing Professor Brannigan's testimony, who will be testifying later in the second panel, I find some of the things that he mentioned there, exactly; the competition—the administrators of the hospital basically can use the system to have more control over what the physicians do and knowledge of what they do; the physicians of course want it to be more readily, handily usable without too much knowledge being disseminated about what they do, and that they, of course, would, as you said, not like to have further security because that impacts, they feel, on their ability to treat. Is that what you have found?

Dr. GARDNER. I really haven't seen that competing interest. Our physicians and administration work very closely together. The physicians really are in the driver's seat, because without them bringing patients to our private hospital, the hospital doesn't have anyone. So they are very responsive to our physicians' group, and I haven't seen that antagonistic type of relationship.

Mr. VOLKMER. Not necessarily an antagonistic relationship; I'd say more a competing interest.

Dr. GARDNER. It may be there, but it isn't obvious to me.

Mr. VOLKMER. To me it was just obvious when you mentioned that you'd like to have more security and the physician says that he can't have more security because he needs the freedom.

Dr. GARDNER. The reason we wanted more security was that was when the Privacy Act came out, and we had a stack that high.

Mr. VOLKMER. Right. And you have that worry, that concern. As Professor Brannigan points out, you have that concern, while the doctor, he has a little different concern. So we do have some different concerns in regard to these types of systems and how they're operated.

Dr. GARDNER. Yes.

Mr. VOLKMER. We're all going to learn, I guess, from it.

Mr. Baker, what convinced you during your time at NIH that these medical expert systems had reached a point where they could be used in the health care system?

Mr. BAKER. I guess from the point of view there, looking at the medically underserved people. Now this, I guess, could be classified from people that are taken care of from nurse practitioners on down to corpsmen in the military.[18] It looked to me like that would be the first potential application of the systems.

I have a real problem right now that unless we start bringing these systems to the marketplace, that they will remain prototypical through the change of the century. We really have to start learning about how to mature them enough where they can be used effectively.[19] It was that idea that took me out of the National Institutes of Health and into this business.

I'd like to make a comment now about developing the business plans for marketing these different expert systems that we look at the whole community of users, and now my notion of marketing this, to use Caduceus as an example, would be the customers of

[18] Mr. Baker edited these sentences to read, "From that point of view, I had concern for the medically underserved people. Now this could be classified for people that are served by nurse practitioners on down to corpmen in the military."

[19] Mr. Baker changed this sentence to read, "We really have to start learning about how to bring about a level of maturity where they can be used effectively."

these systems would range from physicians in the community all the way into the academic institutions. The number of cases that a physician would see—an internist, general practitioner, family physician—in the community where they would need to use Caduceus would probably be in the neighborhood of 1 in 20 cases would be tough enough where they would want to seek the advice of the Caduceus system. Since the tougher cases are always referred to the academic centers, this ratio goes down to about 1 to 10.[20]

I guess that's the picture. Right now I see it only used by physicians and Caduceus used in this manner. If we'd look at the rheumatologists, it would be different. If we'd look at the hypertension expert, it again would be different.[21]

Mr. VOLKMER. Are the concerns of those in the academic community about commercialization of the prototypes concerns relating to constant changes in the medical database, or is it liability questions? What seems to hold them back in moving into the commercial sector?

Dr. GARDNER. Well, I think that when they move into the stage where we have to develop a national consensus, it's like giving up a large piece of their career to the Nation in general. I think that that's a very tough decision for the expert, to turn loose his personal expertise to the Nation and let it be looked at by other experts in the Nation.

Mr. VOLKMER. In other words, he no longer is the only expert or 1 of 3, because of these machines out there, and now we've got 100 instead of 3 experts. Is that what you're talking about?

Dr. GARDNER. That's right. Three or more.

Mr. VOLKMER. Dr. Myers, do you agree with that?

Dr. MYERS. Well, let me just point out what we would envision as that stage of testing and development of our program. It's clearly not there now, as I've emphasized several times, because a lot of diseases aren't even programmed. But assume that they are.

We've always had plans, and we've got volunteers from about, I'd say, a dozen good academic institutions, and I've stressed them because they could evaluate what Mr. Baker is talking about—about a dozen academic institutions who would be very willing to put our program to the field test at the appropriate time, and we would welcome their feedback.

I don't feel that we're giving up anything, so to speak, as we do this. This is a scientific trial, if you will, like trying a new drug or something of that sort.

As I told you, the knowledge base, without the diagnostic program, is already out there in a couple of dozen medical schools, and our only stipulation in giving them this program is, "Look, if you

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[20] Mr. Baker's revision read, "I'd like to make a comment now about developing business plans for marketing these different expert systems. We are looking at whole communities of users. Now my notion of marketing, to use CADUCEUS as an example, would have customers ranging from physicians in the community all the way into academic institutions. The case in the community that an internist, a general practioner, a family physician would see, where they need to use CADUCEUS, would probably be in the range of 1 in 20 cases. That is, 1 in 20 cases would be difficult enough that they would want to seek advice from the CADUCEUS system. Since the tougher cases are always referred to the academic centers, the ratio goes down to about 1 in 10 for those users."

[21] Mr. Baker revised this paragraph to read, "That is my picture. Right now I see it only used by physicians."

find anything wrong with it, find ways to improve it, please give us the feedback."

Mr. VOLKMER. I see.

Mr. Baker, we have another witness in our second panel. In reviewing his statement, it appears that Dr. McDonald is concerned that expert systems are not mature enough to release them for general use. Do you disagree with that view? And I'm not sure that's what he's saying, but we'll find out when he gets here.

Mr. BAKER. In the sense that none of these have been validated, I would say that they're immature from that sense, that none of them represent the medical community on a national basis in terms of the consistency there and the consensus there. That has to be done before they can be marketed.[22]

Mr. VOLKMER. All right. Have you offered any financial assistance to system developers in order to permit validation or verification of medical expert systems?

Mr. BAKER. There is adequate venture capital to cover this stage of the commercialization.

Mr. VOLKMER. OK. Do you have an opinion as to whether or not the FDA should postpone any action on expert systems?

Mr. BAKER. Well, I feel that the initial application of the expert systems will have physician intervention between the computer and the patient and that it really doesn't fall under the Medical Device Act in the sense that FDA does these things. So it's only those systems that act on the patient without human intervention that I think the FDA should be in on.[23]

Mr. VOLKMER. In other words, as long as it remains basically a diagnostic and information system, it's just nothing more than a tool to the doctor.

Mr. BAKER. Right.

Mr. VOLKMER. With that, I'll conclude my questions, and I'll yield to the gentleman from California.

Mr. PACKARD. Thank you, Mr. Chairman. This is a very fascinating hearing.

I wore a Caduceus myself for a while with a "D" on it.

Dr. Myers, Caduceus has programmed approximately 575 diseases.

Dr. MYERS. Yes. A little more now.

Mr. PACKARD. How is that progressing? How long will it take you, in other words, to do what you consider all diseases—750 or so?

Dr. MYERS. In internal medicine?

Mr. PACKARD. In internal.

Dr. MYERS. That depends on how many helpers I have. We've had some slowdown in the last several years, because the faculty of the School of Medicine changed the curriculum to essentially abolish elective time. One used to have, oh, four, five, six, senior medi-

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[22] Mr. Baker's change reads, "In the sense that none of these have been validated, I would say they are immature. None of them represent the medical community on a national basis in terms of a national consensus. This has to be done before they can be marketed."

[23] Mr. Baker's revised paragraph reads, "Well, the initial application of expert systems will have physician intervention between the computer and the patient and it really doesn't fall under the Medical Device Act in the sense that FDA regulates these things. I think the FDA should regulate only those systems that act on the patient without human intervention."

cal students, who can be good data collectors from the literature, for example, working with us, and we made a much faster pace. What we're substituting for that are advanced residents in medicine, but my answer is, it depends on how many helpers.

Now we generally program two or three new diseases a week. One's going in right now while I'm here; we went over it Friday.

Mr. PACKARD. Is most of your work in internal medicine, or have you moved out into other specialties?

Dr. MYERS. Only insofar as they affect the internist. We've got most of the standard psychiatry in there, because internists see a lot of psychiatric patients, of course, and then if you take, say, obstetrics and gynecology, the internist has to know about toxemia pregnancy, cancer of the ovary, cancer of the womb, cancer of the cervix, et cetera. So it's internal medicine very broadly put. But still it's within that limit of 800 diseases.

Mr. PACKARD. Medicine is not an exact science; two and two doesn't always add up to four in medicine; there are differences of opinion even from one textbook to another, from one expert to another. How do you deal with that in terms of providing a specific set of data or information that would give direction to a physician?

Dr. MYERS. Well, it's not too difficult with good study and good experts to draw up that list of manifestations of a given disease—what kinds of abdominal pain occur. I think what you're referring to is the next stage, which is a little more sticky.

We've put two numbers on each of these things, the first number answering the question, "If I make this observation, what diseases do I think of and in what order of importance regarding that manifestation?" and then the other number we put on is, "Given the disease now, not the manifestation, what is the frequency of this manifestation?"

Now one can't do that really quantitatively, and I think that's the burden of your question. We have only five categories—rare, minority, about half, majority, essentially all—and you can fit medical information into those five categories, because they're broad, you see. But if you try to write a 10-point system, as you indicate, medical information is just not that good.

Mr. PACKARD. I'm curious to know—and this would be a question for all three—how far you see this process going down the road. There are just unlimited possibilities, you see, where this could actually become a network that all medical people could plug into. Do you see it getting away from a physician's office or a hospital to where you could have a countywide or a statewide network, or even a nationwide network eventually, where all or any hospital or doctor's office could plug into it and hit the right keyboard and come out with information that is nationally coordinated?

Dr. Baker, do you see something in the future?

Mr. BAKER. The most manageable system would be a central system. That, administratively, would be the most manageable system because as new knowledge comes in, it could be tested, and its effect on the decisionmaking process inside the computer could be assessed, and it could be done very cheaply that way. The telecommunication costs become the big issue, and they're one of the things associated with computers that continue to increase rather than decrease, so that you have to look at the tradeoff between the

telecommunication costs and the cost of maintaining a computer at the site where the decisions are going to be made. I think we've already reached that point.[24]

Most of these systems will run in what we call the microcomputer now, a large microcomputer, the main problem then being getting the continuing education part of the expert up to date, and this would, I still think, be done over the telephone line. So everybody would be working with the same system.[25]

Mr. PACKARD. Dr. Gardner.

Dr. GARDNER. I think a limiting factor in all of this is acquiring the quantitative or computer knowledge from the physicians, and we're going to have to take all of Dr. Myers' information that he'll give us and that anyone else will give us and share that among groups.

Now how that happens physically, whether it's telecommunications or, you know, you've got these little optical discs now that are used for the hi-fi industry that will store 500 megabytes of data. The Poisindex® and the Emergindex® and those things are already on those half a million bytes,[26] and I don't know how many encyclopedias that is—500 million bytes; that's half a billion bytes of information; that's a tremendous amount of information on one of these little devices.

So the way it's distributed, I think, the technology is really helping us.

Mr. PACKARD. It would appear to me that the marketing and the distribution of this kind of information, and also the economics of programming from either a local point of view, or hospital, or a centralized system nationwide, or some variation in between those two would almost drive this eventually, if it's successful, to a point where it would become a nationwide network of information available simply by a terminal in each physician's office.

Then could it lead us to a point where, on minor diseases that would not normally require a physician—common colds or so forth—for a pharmacist to do his thing and then prescribe the appropriate medicine? Do you see it moving down the road to a point where it changes the nature of the physician-patient relationship, et cetera, and all the other ramifications?

Dr. Myers? I'm trying to get a perspective of how far the initial experts in this field feel that this thing is going to go.

Dr. MYERS. Well, I can only guess about this, really. We start at the other end of the horn, of course, building a program for the most difficult cases, you see. But we do envision—and Mr. Baker alluded to this—that if you take the Army and Air Force in north-

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[24] Mr. Baker changed this paragraph to read, "The most manageable would be a central system. That, administratively, would be the most manageable system because as new knowledge comes in, it could be tested, and its effect on the decisionmaking process inside the computer could be assessed, and it could be incorporated very cheaply that way. The telecommunication costs become the big issue, and they're one of the things associated with computers that continue to increase rather than decrease. You have to look at the tradeoff between telecommunications costs and cost of maintaining a computer at the site where the decisions are going to be made."

[25] Mr. Baker changed this paragraph as follows: "Most of the systems will now run in what we call a large microcomputer. The problem then is getting the continuing education part of the expert system into each of the microcomputers, and this would, I still think, be done best over the telephone line. Then everybody would be working with the same system."

[26] Dr. Gardner expanded this to read ". . . those half a billion byte optical discs. . . ."

ern Alaska, where there are medical installations without a physician, that a good corpsman or physician's assistant could use these devices, particularly as screening devices, and if the answer comes back, "Your patient probably has typhoid fever," that corpsman ought to get rid of that patient by air evacuation as soon as possible, you see. So I think it will have that sort of thing.

Now whether they'll go as far as you point out, to pharmacists and nurses who aren't physicians' assistants—I don't mean to deprecate the nurses, but there are two types now—I'm not sure, but certainly there's a potential.

Mr. VOLKMER. Would the gentleman yield?

Mr. PACKARD. I'd be happy to yield.

Mr. VOLKMER. Go one step further. Let's say that I'm at home, and I have my own software, and its compatible, and I figure out the keys, and I plug it in myself, and I put in there that I've got a headache, I just took my temperature and I've got a 101° temperature, that I've got diarrhea, and I've got a little stomach pain in the lower abdomen; tell me what to do.

Dr. MYERS. Well, I hope your system would say, "See your doctor."

Mr. VOLKMER. Yes, but what if it doesn't? It comes back and tells me what to do, and I do that, and I don't get well; in fact, I get real sick and die, and my spouse, again, sues the machine.

Dr. MYERS. Well, there's one real problem with this, as I look at it as a physician. You see, in internal medicine, it varies from place to place, but a very substantial proportion of the patients that an internist sees have usually minor psychiatric illnesses; some have major, but most of them are minor psychiatric illnesses.

Now suppose an hysterical person tried your system. They're not in a position to interpret their headache or many other things, you see, and they're going to get a totally false reading from the computer as to what their illness is about.

So I've been very adamant that any system we build is not to be used except by a professional.

Mr. VOLKMER. Excuse me.

Mr. PACKARD. We could, of course, talk about that concept longer, and maybe we ought not to. Certainly a physician makes his professional judgment based upon his own training and background and the information that he has learned and that's made available to him.

Could a computer—that's the question, and, again, I won't pursue it—could a computer reach a point where it would have access to far more information than the average physician would be able to recall? I think you've already alluded to that, that this is very possible within this kind of a system, and therefore could it make its own decision based upon the same kinds of information that a physician would call upon in recollection or in experience or a variety of other things?

Those are questions that do not necessarily need to be answered now, but they certainly will come at some point in time as this whole process evolves.

One of the tremendous concerns that we're hearing—when I say "we"—my colleagues and I are hearing from our constituents is

the high cost of medical care in today's society, particularly among our senior citizens. It's a major national concern.

Do you anticipate that this system will reduce costs, not just to hospitals? I think it was you, Dr. Myers, that said that Caduceus has already shown where it will save hospitals—I think it was Dr. Myers; maybe not—hundreds of thousands of dollars per year. But I'm interested in what it will save the patient.

Most experience has been in the past that as we become more and more technically sophisticated in our medical care, that it has increased costs; as we have new machines and new diagnostic tools that are used, the physician in the use of those—it just costs more, and that's part of the reasons, along with malpractice insurance and a variety of other reasons, why health care costs have reportedly gone up, by AMA and others.

Is this truly going to be a system that could be expected to reduce health care costs?

Dr. Myers?

Dr. MYERS. We haven't got any measurements on this, but, as I mentioned some time ago in the session, particularly the laboratory radiological questions asked by our system are very pointed, and they're really pertinent to the problem at hand, whereas, you know, sometimes physicians, as I mentioned, have a habit of, "Well, let's make a number of measurements and see what we find," and that costs money.

I would anticipate that these expert systems will reduce moderately the amount of laboratory and allied expenditures in health care.

Mr. PACKARD. But will not the programming of these systems and the use and the plugging into these systems, and having access to that information, simply be one more item on the billing?

Dr. MYERS. Well, yes. Let me give you an example, or at least a potential example.

The development of our system, of course, has been supported by the U.S. Government—the National Institutes of Health, the National Library of Medicine. Now if you'll consider those public costs, and not to be reckoned into our individual costs to a patient or a physician, we can give you a full consultation, depending again on what telephone connections and whatnot, for about $20. Now if we can save one laboratory test for you, then it's cost effective.

So that the actual computer analysis, once you get the system built, is not expensive as you look at overall medical expenses. This is my own anticipation, that it will save one or more examinations per tough problem and therefore will be cost effective, and I think that probably applies to many other——

Mr. PACKARD. Dr. Gardner, do you feel that this kind of a system will reduce the risk of malpractice suits?

Dr. GARDNER. I think it can.

Let me just talk a little about the cost-benefit thing, too. We looked at our pharmacy system and found that it cost us about $40 for each alert that we got, and that shocked us. We then evaluated what it was worth to know about those alerts, and that's a tricky process, and we took a bunch of pharmacists and gave them the costs of hospitals, and it turned out they figured each alert would

have cost $160. So we had a 4:1 benefit-to-cost ratio. So that was helpful.

We also find now, as physicians in hospitals are getting tied more closely together because of the reimbursement situation, that we don't have the physician running a test in the office, sending the patient to the hospital, having the test rerun in the hospital, a whole group of duplication of effort, history. There's a lot of duplication from one place to other; with the ability to share the information from both those locations, since it's one patient, we should be able to be more effective and more efficient, and the incentives are now such that that's happening.

Mr. PACKARD. I can certainly see the benefits to the physician, to the treatment process, to the hospital, and the nurses, of that whole process. My concern is that those benefits will not be just one more billed item on a patient's record or billing, that there in fact will be some efficiencies in the treatment system that are passed on to the patient.

Dr. GARDNER. With DRG's, you get a certain amount, and if it costs you more—I mean, all the incentives now are in place really to have us be more efficient.

Mr. PACKARD. What is the difference, Dr. Gardner, between HELP and Caduceus?

Dr. GARDNER. We've really attacked the world from two different points of view. Caduceus is a diagnostic system; HELP is a data interpretation, alerting, and that sort of system. They're kind of independent right now.

We don't have patient history, and that's the primary source of Dr. Myers' and Caduceus' information. Ours is based on the information that's available to us, quantitative information that's available to us, on patients in a hospital.

We'd love to have that information and eventually, in the next 10 or so years, probably will integrate the Caduceus or its knowledge base into the HELP-type system, but they're quite different systems.

Mr. PACKARD. To what extent should medical schools get involved—or maybe they are—but the primary involvement, into the development, and teaching, and the training of the use of these kinds of systems? Should this be left to the private sector, to the market, like Dr. Baker is involved in, or should this become a part of the medical training process?

Dr. GARDNER. As Dr. Myers has written that book——

Dr. MYERS. Well, as an academician, and my colleagues who helped write this are recommending through the Association of American Medical Colleges that all medical schools have a program in medical informatics in the undergraduate curriculum—that is, the medical schools curriculum.

Now, by medical informatics, we're talking at least 80 percent about computers, and what we would hope and what we recommend then is that each medical school—and they're quite different among themselves—look at this issue and decide how best to introduce the subject of medical computing, I'm going to call it, into the medical school curriculum.

The majority of our medical students now come to medical school with some experience with computers, not the medical aspect but

experience. So they find them comfortable, and they're anxious to use them in regard to medical problems.

So I think in the next decade or two we're going to see quite a change within the medical school extending on into residency education and hopefully continuing education on the part of the physician in this regard.

Mr. PACKARD. In your testimony, Dr. Myers, you mentioned that these programs and this information would be an adviser to the physician; it's not free standing. You also indicated that the physician has the liberty to reject or to disregard the information. Under what circumstances would a physician normally disregard or reject information that was made available?

Dr. MYERS. Well, I think it would be like his reaction to another human physician, a human consultant, who came along and saw that case with him, and sometimes the primary physician will say, "Well, you know, I just don't believe his advice is solid on A, B, C, D."

Now he could do the same thing with the computer program. Having been instrumental in building it, though, I would then say, "Well, you better be pretty careful before you discard some of these recommendations, because they're based on evidence." Now if you put in the wrong evidence, of course, then of course all bets are off, because the machine can't analyze a lot of false data without coming to a false conclusion. I think it's a matter of what we'll call clinical judgment.

Mr. PACKARD. Mr. Baker, how many systems are now being experimented with?

Mr. BAKER. In clinical expert systems?

Mr. PACKARD. Right.

Mr. BAKER. Artificial intelligence. There are about 12 in different stages of development. There's one small system that's already gone commercial. It's embedded in a blood serum protein analyzer. It was developed by the people at the Cleveland Clinic and Rutgers University. It's marketed by Helena Laboratories.[27] That's the only one that's gone to the marketplace.[28]

That one is a very, very small system. The pathologists who use it complain that it doesn't tell them anything about the patient, it only tells them about the proteins, and that they would like for it to be more extensive.

Mr. PACKARD. Do you see where the proliferation of systems, each to accommodate a specific field or a specific specialty, it would require some offices to be programmed into a dozen or two eventually different kinds of expert information systems?

Mr. BAKER. Well, from the marketing point of view, I hope so.

Mr. PACKARD. And if that's the case, then it goes back to our first question; that is, is there some benefit in having a centralized system that will coordinate all this to make it available?

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[27] For further information, contact Dr. Casmir Kulikowski, Department of Computer Science, Hill Center, Busch Campus, Rutgers University, New Brunswick, New Jersey 08903, or Mr. Eric Peterson, Helena Laboratories Corporation, P. O. Box 752, Beaumont, Texas 77704.

[28] Mr. Baker revised this paragraph to read, "Artificial intelligence. I am aware of about 12 systems in different stages of development. There's one small system that's already gone commercial. It's embedded in a blood serum protein analyzer. It was developed by the people at the Cleveland Clinic and Rutgers University and is marketed by Helena Laboratories."

Mr. BAKER. The power of the small computers is increasing so greatly that I think that they'll be able to run a multitude of disease domains or specialties on a single computer, the competition for the use of the computer determining whether or not they need one or more rather than having a separate computer for hypertension, and another one for rheumatology, and another one for internal medicine.[29]

Mr. PACKARD. It would appear to me—and maybe this is a question for all three; and this will be my last question for this panel—that this kind of a system, the computerizing of all kinds of data and information to help those that are involved in the entire treatment process, has several directions that it can go.

One, of course, is the data base that helps a physician make his judgment in terms of a treatment plan; another is to record information on a specific patient that would essentially replace the traditional file on a patient to where it would be a disk or something; that's all it would be.

Do you see that there is potential of this kind of technology leading us to where we no longer need a specific written file on multitudes of patients or where a physician could simply, through electronic devices, put input on to the patient file rather than any kind of record, physical, writing, recordkeeping system, Dr. Myers?

Dr. MYERS. I think it's certainly a potential, and certain institutions—I think Dr. Gardner can answer this better than I—have already made a good start toward the computerized patient record, or hospital record, clinical record—whatever you want to call it. Oh, yes.

You know more about this than I, Reed.

Dr. GARDNER. Well, I think we can do that. A piece of paper is pretty nice and pretty secure. We're all comfortable with it; we can write on it; we can scribble on it.

We find our physicians, if the record is electronic, they will take out scratch pads, if you will, from the electronic record, print it out, work on it, and throw it away.

We heard an advertisement of an insurance company that said, "Paper-free in '83," and we've kind of said, "Paper-free in '93," and that's a goal we're working toward; if we don't get all the way there, I'm not going to be heartbroken, but I think we can get there; yes.

Mr. PACKARD. And security measures are not of concern? I presume that you anticipate those—protection of information—the technology for that will go along with the technology of developing such systems?

Dr. GARDNER. Yes; and we do have to worry about the security of records. Paper records are not secure either, but I think the computer records can be much more secure.

Mr. PACKARD. Thank you, Mr. Chairman.

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[29] Mr. Baker altered this paragraph to read, ". . . on a single computer. The competition for the use of the computer will determine whether or not they need a single computer, rather than having a separate one for hypertension, and another one for rheumatology, and another one for internal medicine."

Mr. VOLKMER. Dr. Gardner, I'd like to pursue that just a little bit further, to understand your system a little bit more. At the present time, are patients' records kept solely on the computer?

Dr. GARDNER. We generate paper records to go in the paper file. So we have both, computer records and a printout from the computer.

Mr. VOLKMER. And a printout that goes in the file?

Dr. GARDNER. That's right.

Mr. VOLKMER. All right. Now we have all heard that the doctor makes his rounds usually in the morning and in the afternoon he has his office hours. At least that's the way it works back home and has for generations, as far as I know.

Let's say he's making his round. You have the nurses' station. Does he get a printout of each, or does he just look at a display?

Dr. GARDNER. It depends on which physician. If we're in the ICU, the only place you can get current information is from the computer terminal, because the pieces of paper aren't filed in the chart. So they go to the computer terminal to get the data. Some physicians out on the wards go to the computer terminal; some go to the paper record.

Mr. VOLKMER. And in the paper record, he'd get a printout—up-to-date printout of the patient.

Dr. GARDNER. Right.

Mr. VOLKMER. That's going to take me one step further, and that is, now I'm a physician, and I decided, "Heck, why do I go in the hospital? I'll go down to my office and I'll just plug in, and I'll get it on my computer." Is that correct?

Dr. GARDNER. He could; yes.

Mr. VOLKMER. I mean to say, whether he wants to make the round or not.

Dr. GARDNER. I hope physicians are always looking at the patients.

Mr. VOLKMER. I know, but it could be that he could make a determination on some patients, if the treatment is fine, and everything's fine, and there's no change, or the change is just as it's supposed to be, and if he wants to make any changes or corrections in that, he could do it by telephone or, theoretically, in the future, by the computer—could he not? Just punching it back in.

Dr. GARDNER. Yes. They do it right now by telephone. They'll call in and say, "Hey, call me the lab data back," and make a decision at 3 in the morning to give a unit of blood or whatever, and that's already happening.

I guess the computer might be construed to make that easier, but there's a tremendous responsibility in that physician to look at and care for the patient. We have house staff at the hospital, too, additional physicians who help.

Mr. VOLKMER. Now how does the physician, other than, I guess, by reviewing the printout, without the paper—how would he authenticate that electronic record as far as legal purposes are concerned?

Today, a lot of physicians, you know, when they go around, they'll initial that they've been by that morning. Now he's not going to initial that, I guess, or would he just put a thing in the computer?

Dr. GARDNER. You can put an electronic signature in, yes. We have our nurses doing that now. They sign off electronically.

Mr. VOLKMER. I'd like to ask one last question to Dr. Myers and Dr. Gardner.

What efforts, if any, have been made to set standards for developing medical software?

Dr. MYERS. I can't really answer this very basically because we're working on our own individual program, and we have nothing to compare it with at the present time, you see. I don't know any program like it, either in this country or overseas. So we have what I might call our own internal standards, I suppose, but they're not applicable to other programs at this time.

Again, I think you're in a better position to perhaps answer this, Dr. Gardner.

Dr. GARDNER. Well, that's a hard question to answer. There's the medical knowledge, standardizing medical knowledge, and we have made some local and some regional efforts at that in, say, interpretation of pulmonary function. We have come up with some standards, had local reaction to that, and then had a regional conference, have just recently updated that. We're even looking, through the American Thoracic Society, at perhaps making some of those criteria national standards, or at least recommendations, a starting place from which someone can work.

That is done very little with the medical system as it currently exists, and that needs to be done more, so that if you've got this set of conditions, these are things you ought to do, or this is the interpretation you ought to make.

I can tell you from going from 26 pulmonary function labs in the United States, there were literally 26 different projections of what my lung function should be and huge variations in the measurement capability, and that needs to be tightened up, and I think the computer can offer us some opportunity there. But as far as standards, I don't know.

Mr. VOLKMER. Mr. Baker.

Mr. BAKER. The standards that I see being developed are in the knowledge base and in the decisionmaking process for the AI systems. Right now, there's only one of these projects in artificial intelligence experts that is planning to do this, and this is the one from Missouri that Dr. Lindberg [30] has taken to the National Library of Medicine, and they are planning to do, with public funds, the validation of the rheumatology knowledge base, and that, I think, will become a standard.[31] There are private funds available to do it for other systems.

Mr. VOLKMER. What about the AMA? Is there any activity, that any of you know? Any committees set up by the AMA to review this? None, to your knowledge?

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[30] Dr. Donald A.B. Lindberg is Director of the National Library of Medicine at the National Institutes of Health.

[31] Mr. Baker clarified this sentence: "Right now, there's only one of these projects in artificial intelligence expert systems that is planning to do this. That is the one from Missouri that Dr. Lindberg has taken to the National Library of Medicine, and they are planning to do the validation of the rheumatology knowledge base with public funds. That process, I think, will lead to a standard."

Dr. MYERS. They have an information system, as probably you know, where you can get information about drugs, drug-drug interaction, but I don't know of any activity on their part that touches on what we've been discussing here recently.

Mr. PACKARD. Would the chairman yield, please, for a moment on that?

Mr. VOLKMER. Yes.

Mr. PACKARD. Let me carry that to the FDA and the comments that have been made on that also, as monitoring or certifying agency or so. Your comments have been that this is not a device that would fall under the act. Who then should monitor and who should be the agency or the individuals that will monitor the accuracy and the information generally that's used in these expert systems?

Dr. MYERS. Well, again, I think I can only conjecture, but I think you implied one mechanism when you asked did the AMA have a committee or any group looking at this. My answer would be professional societies, just as we monitor quality in other respects—who's eligible for board certification, for example, which is a purely private thing in regard to medical education.

We have had some overtures actually from the American College of Physicians, which is the internists' professional association, of having an interest in our program. We never got down to details enough to say, "Well, will this be quality evaluation as well as other things?" but I'm sure that the American College of Physicians wouldn't be interested in any program that did not have good quality and controllable quality.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. VOLKMER. To continue on just a little bit, as we know, computers are basically machines. Dr. McDonald, in his written statement—who will be on the next panel—notes that doctors themselves often disagree about subjective points in a patient's condition, citing the loudness of a heart murmur. For different physicians it means a different thing, and it projects even differently. He goes on to say that this may cause an expert system to issue different interpretations of a patient's condition.

What efforts are underway to standardize medical terminology so that these information systems communicate with a common vocabulary? How would you address that, Dr. Myers?

Dr. MYERS. Well, it's a subject that's pretty close to my heart. When we've built these 4,100 manifestations of disease, all kinds of symptoms, physical signs, et cetera, we have done our very best to make those expressions explicit, accurate, not ambivalent.

Now I don't know how much I'm going to convince my colleagues as this gets more and more broadcast, but this is a medical terminology we should accept, but I feel this very definitely—we all need to speak the same language, and I agree with Dr. McDonald that physicians don't always do this.

Now in answer to the other part of your question, in our expert system at least, if the physician enters a few wrong observations, but most of them are valid, he's going to get a good analysis, and it's only when you put in a lot of wrong or false information that you're going to get a faulty analysis, but of course that happens

with this computer up here, too, you see, so I don't have to apologize for that.

Mr. VOLKMER. OK.

Dr. Gardner, I'd like, if I can, just to try, in laymen's language, to review basically what your system does as far as the way I see it—correct me if I'm wrong—that is, basically an informational and auditing system; it's not a diagnostic system in itself—is that correct? Correct me if I'm wrong.

Dr. GARDNER. Well, it provides interpretations. It doesn't provide a diagnosis that you have congenital heart disease or some other problem.

Mr. VOLKMER. Right.

Dr. GARDNER. Interpretation and alerting system, I would say.

Mr. VOLKMER. Right. But basically the physician, when a patient is either seen at the office and sent to the hospital because he needs to or is going to have to go in, makes a decision on the treatment originally—correct?

Dr. GARDNER. Yes.

Mr. VOLKMER. And basically, at that time, your patient's history, if they've never been a patient at the hospital, is all entered into the computer along with the prescribed treatment, et cetera.

Dr. GARDNER. Yes.

Mr. VOLKMER. And that's when the computer starts taking over, and then as the data comes into the computer, whether it's from the lab or from nurses' notes on the patient's condition, or the physician's—whatever it is—that all goes in, and that is monitored basically by the computer. Is my understanding correct?

Dr. GARDNER. Yes.

Mr. VOLKMER. And then if the computer runs into something which it feels is incompatible as far as treatment is concerned, it will alert?

Dr. GARDNER. That is correct.

Mr. VOLKMER. Will it do the positive—turn around and say, "Hey, you're not doing something that should be done; you should be doing this?" Would it do that?

Dr. GARDNER. It could. We aren't using it for that function right now.

Understand that we're probably—Dr. Myers says he's 80 percent of the way; we're probably 5 or 10 percent of the way as to where we want to be, and we're covering a very small part of what needs to be done. It eventually can do that, and we want to do that, but at the moment it isn't.

Mr. VOLKMER. It will do more for those in the ICU than it will out on the floor?

Dr. GARDNER. Yes; because they have more data.

Mr. VOLKMER. Right. And there's constant monitoring of vital signs, et cetera, which is not on the other.

Dr. GARDNER. Right.

Mr. VOLKMER. Very good. I think I understand a little bit better then.

I want to thank all three of you. If we have any additional questions, we'll submit them in writing and appreciate your returning the answers to them.

Dr. Gardner, the other one about the cost savings, if that is too great a thing, just say so, if it's too much difficulty.

Dr. GARDNER. I'll give you an estimate.

Mr. VOLKMER. I don't want you to go out there and spend a lot of money at the hospital to come up with some information for us. I don't want to do that. I don't want to cost your savings.

So, with that, I'll excuse these panelists, and we'll start with our second panel.

The subcommittee welcomes Vincent Brannigan, associate professor of consumer law at the University of Maryland. Professor Brannigan has worked extensively in analyzing the problems of liability as applied to use of computer software, and we have asked him to discuss that with us today.

Dr. Clement McDonald from the University of Indiana is director of medical information sciences at the Regenstreif Institute and also serves as cochairman of the public policy committee for the College of Medical Informatics. He has been invited to testify on how we can verify that a computer system like those discussed earlier will work accurately as well as other issues created by the use of these systems.

The subcommittee also welcomes Mr. Robert Belair of the law firm, Kirkpatrick & Lockhart. He will give us the benefit of his expertise in privacy issues as they relate to the computerized storage of personal medical data. Mr. Belair serves on the Office of Technology Assessment Advisory Board on Telecommunication Privacy and has assisted in development of model legislation for protecting medical information.

As I noted earlier, your written statements will appear in the record in their entirety. You may either summarize in your oral testimony or review in full, however you so desire.

Professor Brannigan, you may begin.

STATEMENTS OF VINCENT BRANNIGAN, ASSOCIATE PROFESSOR OF CONSUMER LAW, UNIVERSITY OF MARYLAND, COLLEGE PARK, MD; CLEMENT McDONALD, M.D., REGENSTREIF INSTITUTE, INDIANAPOLIS, IN; AND ROBERT BELAIR, KIRKPATRICK & LOCKHART, WASHINGTON, DC

Professor BRANNIGAN. Thank you very much. May I acknowledge thanks for your invitation and also the contributions to the work of my coauthor, Dr. Ruth Dayhoff, assistant professor of biomedical computing at Georgetown University.

The whole liability issue is a critical problem in the area of computer software for two reasons, I think. One is that the level of uncertainty is fairly high and, second, that liability is often used to create tension in certain kinds of relationships for ulterior motives.

I think there are three critical legal issues involved in medical computer software. First is liability for the use or nonuse of medical computer systems; second is Federal regulation of medical computers as medical devices under the Food and Drug Act; and third is the interrelationship of artificial intelligence and expert systems with State-mandated limitations on the practice of medicine. Given time limitations and the committee's jurisdiction, I'm restricting my comments to the first two areas.

The areas of liability and regulation are directly related. There is no doubt in my mind that the decisions reached by this committee and the Food and Drug Administration concerning the regulation of medical computer systems will have a direct effect on the liability issues.

First, as to liability, in many areas of medical malpractice liability there's enormous confusion, difficult factual issues of proof, causation, and responsibility. However, in the area of injuries purportedly caused by medical computer systems, the facts are even more difficult and the answers even more uncertain.

Computer systems are not standardized items, and even similar systems are often altered in the field by users. They can be altered without trace.

Some producers have assumed that negligence is standard for medical liability. I don't think so. I think the standard will be strict liability if we can meet the other criteria under section 402(a).[32]

I believe that the rationale for strict liability is that computer programs can be owned, they exist through time, they have errors which can be corrected. They are, therefore, products in that narrow sense.

Once it's accepted that computer programs are products, liability would be strictly imposed if the other requirements are met.

The most important issue, and one we've addressed this morning, is how the system is used. First, the computer system can act as a background resource for the physician. In this case, the computer doesn't reach the patient, and liability will probably follow standard malpractice concepts. This is based on the Restatement of Torts [33] requirement that the product reach the consumer.

In the second case, the computer system interacts directly with the patient. These are basically your various devices with embedded computer systems. I don't think there's a great deal of question, those are clearly devices, products, et cetera, not very complex.

The third issue that I think is the growing issue, the issue that obviously concerns this committee, is where the computer is producing output which the physician relies on without further checking. This category would include most laboratory results, patient records, and similar items, and when reliance on the data is automatic, and errors can be catastrophic, and I believe in this area strict liability will be imposed.

I think, as the committee noted this morning, the tendency to rely on data increases as the reliability of data increases, and therefore I believe—and I think I wrote this in my 1981 Law Review article—that this will be an expanding category of knowledge. That is, physicians don't check thermometers any more; at one time they did; now they don't; and as data becomes more reliable, you do rely on it more. So this is a flexible, not a fixed, category of data.

The second problem is to define what constitutes a defect in computer software. I go through in quite some detail some of the issues

[32] Restatement (Second) of Torts, Section 402(a).
[33] *Ibid.*

involved in a defect. I think the primary thing to understand is that there can be logic errors and there can be programming errors. There can be errors in the underlying system design or errors in just putting the system together and debugging it. Debugging a computer system is an incredibly time-consuming and very expensive task and is often today not done in its entirety except in the most expensive, most valuable systems.

This raises the issue of quality control in many ways. I believe that liability with standards will take a substantial time to develop. One of the areas that was raised this morning is liability for failure to use a computer system, and I think this could arise in a couple of fundamentally different ways.

The first would be failure to use a computer system to check on specific problems which can be found in standardized medical data bases, particularly drug-drug interactions. I have proposed that if there is a first case it will be in the failure to check pharmaceuticals, because that can be done automatically.

The other area is the ordinary failure to maintain accurate patient records of the type which a computer system could provide. The number of cases that have occurred due to the inadequacy of standardized handwritten patient records are significant, and in these two areas I think there will be liability potential for hospitals that fail to use systems.

The liability problem is very real. Short of passing a general products liability bill, which I certainly don't support, the most direct effect this committee can have on the liability issue is its instructions to the Food and Drug Administration regarding the regulation of medical computer systems as devices.

I think the reason for this is that, particularly in my course—in my research on the interaction of liability and regulation, the implication that a product is substandard according to a regulatory environment is essentially liability, per se, and the FDA's concept of how to regulate these software systems sets standards for them which are both unrealistic and, I believe, would be detrimental to the development of the technology.

I think there are certain basic principles which should control all legal efforts in this area. The first is protection of patients from the unreasonable risk of injury. I teach consumer law, and my orientation is toward the patient.

Second, there should be a search for relative improvement in medical care, not absolute perfection. This is a real problem with the FDA approach. They want to know that your machine is perfect, not that it's better than, let's say, not the top quality or even the average doctors but the lowest quality doctors we find out in the system.

Third, any system should avoid entrenching existing institutions, whether governmental, industrial, or professional. The role of regulation is, in effect, cartelizing certain industries is well known, and I believe it could happen in this area.

Fourth, in any implementation of a computer system, there must be a financially responsible party. This is a major issue in the attempts by various parties in the computer system field to disclaim liability to one another to the point where they think the consumer will be left holding an empty bag.

Finally, in terms of patient therapy, there must be a party clearly responsible for the proper operation of the system.

Compliance with these principles is difficult under the current legal system, particularly under the FDA's approach. I will mention that, having taken a quick look at the FDA's response, this is in the area of logic that I would describe as proof by blatant assertion. That is, it's a device, therefore we regulate it, and I know that they have deeper thoughts than this.

I've had the full cooperation of people at FDA in discussing this. But certainly their argument as to why it's a device I find inadequate. I've furnished the committee with a subsequent paper which I delivered last Wednesday at the AAMI on my concerns in this area.[34] I don't think they have jurisdiction over freestanding software.

I've brought only a limited number of copies, but I'd be happy to supply additional ones.

But I think the product-oriented system that medical devices operate under is inappropriate for medical software. It doesn't work the way other products work, it doesn't exist the way other products exist, and therefore I think it will require—I'm not opposed to regulation of software, as such.

I think the protection of public health and safety requires sensitive thinking about it, but just as devices were not drugs and therefore required amendment to the statute,[35] software is not a device and I believe will require amendment to the statute, and I think more sensitive and sensible regulation could be proposed. I think this will have a direct effect on liability.

The basic problems with the product-oriented approach are that it tends to limit development in the field to those companies which are both adept at the technology and sophisticated in dealing with the regulatory authorities. Since this is a technology which is overwhelmingly coming out of universities, the second simply doesn't occur.

Second, product regulation tends to centralize production in a small number of firms. The first firms through—we've noticed this in a number of areas—essentially can monopolize or dominate the market—I don't want to use the term "monopolize"—because of the entry barriers they create to subsequent players in the game.

Third, regulation of software tends to limit the flexibility of the user in adapting the device to local conditions. This is a problem with the device-oriented regulations of the FDA. Your ability to adapt to local conditions, as opposed to local patients, is very limited.

Fourth, under the current concept of product liability and the way medical software is distributed, liability for defective software is diffuse. Small companies may not be financially viable in this area due to the inability to obtain adequate liability insurance. I think this should be taken into account when planning the regulatory structure.

Fifth, some software will be exempt from regulation. The reason no one from FDA goes out to the University of Utah is that their

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[34] See page 139.

[35] Medical Device Amendments of 1976, 21 USC 301(90 Stat. 539-583).

own regulations don't cover things which the hospital makes for itself. So there will be loopholes only covering—if you were only covering one of the panelists in the prior panel but not all three.

Finally, I think their orientation—and this is something I'm just making from their statement—is oriented toward systems which are fairly rigid, written in programming languages which don't allow flexibility by the user. They're oriented toward a COBOL-style [common business oriented language] financial system rather than the flexible user-oriented systems which are—the Government, for example, has supported the Veterans Hospital; it's based on the MUMPS [Massachusetts General Hospital Utility Multi-Programming System] computer language. I am the general counsel of the MUMPS users group, so I have a special interest in its ability to participate in this area.

My proposal would be that we register the use of these systems in a centralized location. That is, everyone who is using them should tell an appropriate office—I have no problem with it being the Food and Drug Administration—what they are doing, and that they are doing—and as much information as is conveniently available, so that we don't have to ask the questions of how many systems there are that are out there, and that essentially at this point the regulations stop at that point, that we know who's operating out there using artificial intelligence in medical computer systems, so that if we find a defect that might be common to multiple systems we can quickly notify the individuals.

I assure you that the people who are using these systems are very interested in getting them improved and fixed. They share a lot of knowledge, and I believe this system would be adequate. I think it would focus regulation on the parties actually controlling the use of the software. It would clarify responsibility for control of the software and the potential uses to which software could be put.

Liability would be strictly imposed on the using hospital. Most of these systems are hospital based. It's the place best able to evaluate what level of oversight is needed. This directly addresses the issue of relying on the data, what level of reliance could be set at a local level.

By concentrating liability at the user level, there would be an increase in competition rather than a reduction since the financial viability of the producer of the software would no longer be an issue. And, finally, the users—these are hospitals—are already subject to regulatory control. They're familiar with the requirements of regulatory authorities. They deal with the Federal and State regulatory authorities on a regular basis, and I believe we would obtain economies of scale in regulatory compliance alone.

I'm not suggesting that medical software be exempt from either regulation or liability. However, in the case of this unique product, the public interest would best be served by the imposition of strict liability at the level of the user, complying with a modest level of regulation on the same party. This combination would provide the optimum mix of protection of consumers with minimum restrictions on the development of this revolutionary technology.

Thank you very much.

[The prepared statement of Professor Brannigan follows:]

TESTIMONY OF VINCENT BRANNIGAN

TO THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

CONCERNING THE USE OF COMPUTERS IN MEDICINE

MARCH 18, 1986

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BIOGRAPHICAL SKETCH -- VINCENT BRANNIGAN

Vincent Brannigan is Associate Professor of Consumer Law at the University of Maryland where he teaches a course on the interaction of government regulation and products liability. In 1984, he conducted a year-long project in medical computer law as a Visiting Scholar at the Massachusetts Institute of Technology, and at the Center for Medical Computing Science, University of Frankfurt, Germany. He has authored more that forty publications, including;

"Medical Informatics: The Revolution in Law, Technology and Medicine," American Journal of Legal Medicine, March 1986.

"Liability for Personal Injuries Caused by Defective Medical Computer Programs," American Journal of Law and Medicine, 1981.

"Principles for Patient Privacy Protection: USA and Germany", Proceedings of the Fourth World Conference on Medical Informatics, Amsterdam, 1983.

"Compensation v. Regulation: The problem of Medical Computer Software," Journal of Consumer Policy, Vol 6:475-481, 1983.

"Patient Privacy, A Consumer Protection Approach," Journal of Medical Systems, 1984.

"Remote Telephone Access: The Critical issue in Patient Privacy Protection," Proceedings of the Eighth Symposium on Computer Applications in Medical Care, 1984.

"Acceptance Testing: The Critical Issue in Software Acquisition", IEEE Transactions on Biomedical Engineering, 1985.

Professor Brannigan serves as Vice President of the German Society for Medical Computer Law, General Counsel of the MUMPS USERS GROUP, and formerly served as General Counsel of the Symposium on Computer Applications in Medical Care. He has a B.A. from the University of Maryland, a J.D. from Georgetown University, and is a member of the Maryland and D.C. Bars. He is Of Counsel to the firm of Lamb and Ochs, and a consultant to the National Association of Home Builders Computer Software Review Project. He recently addressed the American Bar Association on the topic: Can Computers, High Technology, Commit Medical Malpractice? His wife and co-author on some of his articles in the area of medical computing is Ruth Dayhoff, M.D., Assistant Professor in Medical Computing and Biophysics at Georgetown University Medical Center and a founding fellow of the American College of Medical Informatics.

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ORAL TESTIMONY OF PROF. VINCENT BRANNIGAN TO THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY 3/18/86

I have been invited to address the committee on the issue of liability in regards to the use of medical computer systems. The medical computer liability field is in its infancy. To my knowledge there are no decided cases. The fear of liability is used for every purpose from promoting the use of computer systems to arguing against them. It is my opinion that liability is only one of several closely related critical legal issues involved in the introduction of computer systems to clinical medicine. None of the major issues can be addressed in isolation

The three issues are:

1) Liability for the use or non use of medical computer systems.

2) Government regulation of Medical computers as medical devices under the Food and Drug act.

3) The interrelationship of artificial intelligence and expert systems with state mandated limitations on the practice of medicine.

Given my time limitation and this committee's jurisdiction I will restrict my comments here to the first two. I have submitted two written statements.

The areas of liability and regulation are directly related. There is no doubt in my mind that the decisions reached by this committee and the Food and Drug Administration concerning the regulation of medical computer systems will have a direct effect on the liability issues.

First, as to liability. In many malpractice or products liability cases there are difficult factual issues of proof, causation, and responsibility. In the case of an injury caused by a medical computer, the facts can be even more cloudy, and the answers even more uncertain. Computer systems are not standardized items, and even similar systems have crucial differences. Software is ephemeral; it is often changed in the field by users, and can be altered without trace. A program is often the product of many hands, who leave no trace of their individual efforts.

Some producers have automatically assumed that negligence, is the appropriate test for injuries caused by computer programs. I disagree. There is a strong argument that computer programs are products, subject to strict liability. Despite their intangibility, programs show all of the other characteristics of a product. Computer programs can be owned, they exist through time, they have errors, which can be corrected. They can be

passed from person to person.

Once it is accepted that computer programs are products, liability will be strictly imposed in most jurisdictions if the other requirements are met. The most important issue is how the system is used. First, the computer system can act as a background resource for the physician. In this case the computer does not "reach" the patient and the liability follows the typical malpractice approach of reasonable care. In the second case the computer system interacts directly with the patient. Traditional strict liability is appropriate for devices which are directly computer controlled such as CAT scanners or intensive care monitoring. It is the third case which poses the unique problems. There the computer is producing the output which a physician relies on without further checking. This category would include most laboratory results, patient records, and similar items. In these systems reliance on the data is automatic, and errors can be catastrophic. In such a situation a strict liability standard for errors is appropriate.

The next problem is to define what constitutes a "defect" in computer software. Unlike many other products, there may be no clear way to define a product as defective. Computer programs are not built to blueprints. They are built to a system design which is normally changed continuously as the system is being installed. Many are one-of-a-kind installations where the design, production and quality control phases are merged together. Systems are often created in joint efforts between medical users and software houses. Systems are often put into service for field testing despite the presence of errors. Sometimes testing the system does not reveal the defect; only prolonged use of the system will. Since error correction is labor intensive, it is typical to leave a certain number of "bugs" in any system, to be corrected, over time, as the system is used. The term "maintenance" which in most fields is simply keeping the machine up to specifications, is used in the computer field to describe this continuous error removal process. Because of this process, there may not be the clear cut separation between manufacturer and user.

Liability standards will take a substantial time to develop. One major area of concern is liability for failure to use a computer system. I think this type of liability could arise in fundamentally different ways. The first would be to fail to use a computer system to check on specific problems which can be found in standardized medical databases, such as drug-drug interactions, or the latest contraindications to various types of therapy. The other area is the ordinary failure to maintain accurate patient records of the type which a computer system could provide. Allergies, patient histories and prior complications are all easily stored in computers, but can take substantial time to recall in a manual system. Automated medical

information systems are clearly the state of the art, and without them a hospital or doctor would be vulnerable under the leading case of the T.J. HOOPER.

To sum up the liability exposure, the problem is real and immediate. Short of passing a general products liability bill, which I do not suggest, the most direct effect this committee can have on the liability issue is in its instructions and oversight to the Food and Drug administration regarding the regulation of medical computer systems as devices. The liability and regulatory issues are intertwined because both legal concepts serve the same conflicting goals; how do we promote the advancement of medical technology while maintaining the maximum of patient protection, both physical and financial?

The primary question in both areas is what legal approach should be used to control clinical software? I am not persuaded that the current Food and Drug Act actually covers software. But I am confident that the product oriented approach of that act would be both ineffective and hostile to the development of the technology. The legal system should not attempt to define in advance what direction this technology will take. However, the liability and regulatory policies should be coordinated.

There are certain basic principles which should control all legal efforts in this area. First is protection of patients from the unreasonable risk of injury. Second, there should be a search for relative improvement in medical care, not absolute perfection. Third, any system should avoid entrenching existing institutions, whether governmental, industrial or professional. Fourth, in any implementation of a computer system there must be a financially responsible party. Fifth, in terms of patient therapy there must be a party clearly responsible for the proper operation of the system.

Compliance with these principles is difficult under the current legal system. Under the current regulation of medical devices and drugs, the federal government controls the manufacture and labelling of devices and drugs, and the states control the use. The division is similar in products liability, where the producer is strictly liable, but the user is subject to a test of negligence. For all of the reasons I mentioned earlier, the technological development of this field has made this distinction obsolete. For example, a hospital worker sits down at a terminal. It makes no functional difference whether the computer is located in the same hospital, across the country, or in another country. Likewise, it makes no difference whether the system is produced in his hospital, or purchased on the outside. It is of no importance if the system is one of a kind or one of a group. Yet both the regulatory and liability systems fasten on these irrelevant distinctions to impose widely different levels of regulation and liability.

The primary policy choice for this committee is between the product oriented concept of the current medical device legislation act, and a user oriented regulatory approach suited to the nature of this technology.

The primary problem with the product oriented approach is that it tends to stifle all of the attributes which make computer software such an exciting technology. Product oriented regulation tends to limit developments in a field to those companies which are both adept at the technology and sophisticated in dealing with the regulatory authorities. We can get the medical equivalent of the Pentagon's $600.00 hammer because ingenuity in dealing with the regulator is the key business attribute.

Second, product regulation tends to centralize production in a small number of firms. The first handful of firms approved can divide up the market. Regulatory approval is a substantial entry barrier. There are only a small number of viable hardware producers in the computer field, compared to the vast number of software houses. This is due to the different economies of scale in starting up operations. The regulatory burden could be crippling to small, innovative companies. It is precisely these innovative companies which are the strength of the computer field. Many of the most innovative producers are universities and hospitals. There is a tradition of sharing breakthroughs and software which could disappear if regulated.

Third, regulation of the software tends to limit the flexibility of the user in adapting the device to local conditions. While the food and drug act provides for customization of the device to a patient, it does not provide for customization to the institution, which is often critical in clinical software. Modifications of systems by producers in light of system failures or increased knowledge would be slowed by the need for regulatory approval.

Fourth, under the current concept, liability for defective software is diffuse. Small companies may not be financially viable. Insurance in this area is becoming unobtainable. The liability exposure is determined by traditional strict liability with contractual disclaimer and indemnity.

Fifth, some software will be exempt from regulation, because it is created by the using hospital. Software can also disappear from the regulatory system because of the demise of the producing company, while the software is still in use.

These deficiencies can best be addressed by recognizing that software is a fundamentally different item from a scalpel or an x-ray machine, at least at the current state of the art. When

medical software is marketed like Wordstar or Lotus 1-2-3 product oriented regulation may be appropriate. I do not suggest ignoring the potential risk. My proposal is instead to adopt a regulatory system oriented towards the user of the software, rather than the producer, and fix the liability for defective software at the same point. Such a proposal would involve registration of each user location.

This proposal would 1) focus regulation on the parties actually controlling the use of the software. It would clarify responsibility for control of the software and the potential uses to which software would be put. 2) Liability would be strictly imposed on the using hospital, as the place best able to evaluate what level of oversight is needed. By concentrating liability at the user level there would be an increase in competition, rather than a reduction, since the financial viability of the producer would no longer be an issue. 3) The users are already subject to regulatory control. They are familiar with the requirements of the regulatory authorities.

I am not suggesting that medical software be exempt from either regulation or liability. However, in the case of this unique product, the public interest would best be served by imposition of strict liability at the level of the user, combined with a modest level of regulation on the same party. This combination would provide the optimum mix of protection of consumers with minimum restrictions on the development of this revolutionary technology.

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WRITTEN TESTIMONY OF PROF. VINCENT BRANNIGAN TO THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY MARCH 18, 1986
Part I

LIABILITY AND REGULATORY ISSUES IN MEDICAL COMPUTER SOFTWARE

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I have been invited to address the committee on the issue of liability in regards to the use of medical computer systems. The medical computer liability field is in its infancy. To my knowledge there are no decided cases. The fear of liability is used for every purpose from promoting the use of computer systems to arguing against them. It is my opinion that liability is only one of several closely related critical legal issues involved in the introduction of computer systems to clinical medicine. None of the major issues can be addressed in isolation

The three issues are:

1) Liability for the use or non use of medical computer systems.

2) Government regulation of Medical computers as medical devices under the Food and Drug act.

3) The interrelationship of artificial intelligence and expert systems with state mandated limitations on the practice of medicine. I have included a separate written statement on this issue.

The areas of liability and regulation are directly related. There is no doubt in my mind that the decisions reached by this committee and the Food and Drug Administration concerning the regulation of medical computer systems will have a direct effect on the liability issues.

The most important changes in the legal system are due to the much wider need for information which computers provide. The information is of many types. There is information about the patient, about the illness and about the scope of treatment. With computerized medical information systems, comparisons are possible among physicians, hospitals and specialties. The use of expert systems raises even more dramatic possibilities of changes.

The topic of this presentation is liability. For the purpose of this presentation the widest possible definition will be used to include not only physical injury to the patient, but also invasion of privacy, infliction of emotional distress and

other non-physical injury. This presentation is designed, not to give a primer in the law, but to describe the background of medical information systems and how they can lead to a liability problem.

The medical computer liability field is in its infancy. The few cases which have become known have not gone to trial. However, the explosive growth in medical computer systems has occurred with little input from the legal sector.

In many malpractice cases there are difficult factual issues of proof, causation, and responsibility. In the case of a computer caused medical injury, the facts are even more cloudy, and the answers even more uncertain. Computer systems are not standardized items, and even similar systems have crucial differences. Software is ephemeral, it is often changed in the field by users, and can be altered without trace. A program is often the product of many hands, who leave no trace of their individual efforts. It is worth noting that S.100, the Kasten products liability bill now before Congress, would not apply to a computer program. The act defines a product as a tangible item with intrinsic value. Computer programs are not. It is possible that an entire jurisprudence must be developed to deal with the unique aspects of computer related injury.

CONCEPTS OF LIABILITY

In a 1981 article in the AMERICAN JOURNAL OF LAW AND MEDICINE I wrote extensively on the liability for personal injuries caused by a defective medical computer program.(1)

In conducting research for that article, it was striking how many people automatically assumed that negligence, rather than strict liability would be the appropriate test for injuries caused by computer programs. They seemed preoccupied with the intangible nature of the program, and that the output of the program was a service. There is a strong argument that computer programs are products, subject to strict liability. Despite their intangibility, programs show all of the other characteristics of a product. They can be owned, they exist through time, they can have errors, which can be corrected. They can be passed from person to person.

In some sense, programs are like books, but unlike books in most circumstances, they can be the direct source of injury. In this sense they are essentially the instructions to a machine. Like the camshaft on a car, the instructions are set the machine will do what it is told.

Once it is accepted that computer programs are products, liability will be strictly imposed if the other requirements are met. The most important requirement is probably that the defect

"reach" the consumer. This requires extensive analysis. The first issue is to define what the computer system does; there are basically three possibilities. First, the computer system can act as a background resource for the physician. In this case the computer doesn't "reach" the patient and the liability follows the typical malpractice approach of reasonable care. In the second case the computer system interacts directly with the patient. Traditional strict liability is appropriate for devices which are directly computer controlled such as cat scanners or intensive care monitoring. It is the third case which poses the unique problems. This is where the computer is producing the output which a physician relies on without further checking. This would refer to most lab results, patient records, and similar items. In these systems reliance on the data is automatic, and errors can be catastrophic. In such a situation a strict liability standard for errors is appropriate.

A second major issue is to define what constitutes a "defect" in a computer system. Errors tend to be of two types, logic errors and programming errors. The problem is, apart from the most egregious mistakes, it can take a thorough investigation to determine what type of error is present. Unlike many other products, it is often difficult to separate a design from a production defect in a computer system. Computer systems are not built to blueprints. They are built to a system design which is normally changed continuously as the system is being installed. Many are one of a kind installations where the design and production phases are merged together. Systems are often put into service for field testing despite the presence of errors. Sometimes testing the system does not reveal the bug, only using the system. Since error correction is labor intensive, it is typical to leave a certain number of "bugs" in any system, to be corrected, over time, as the system is used. The term "maintenance" which in most fields is simply keeping the machine up to specifications, is used in the computer field to describe this continuous error removal process.

A logic error can arise in a very simple way. For example, at one hospital the computer system provided the complete bed assignment system. Beds are a hospital's stock in trade; keeping track of them is often critical to cost control. This hospital divided its services into two groups, those with beds, such as surgery, and those without beds, such as radiology. The bed allocation system was connected to the pharmacy system, which packaged drugs for individual patients and sent them to the floor. When a patient was transferred directly from one bed service to another, the bed control and pharmacy records were updated to show the new location. When a patient was transferred to a non bed service, the bed control records were changed to show the temporary status, but pharmacy was unchanged because the patient was expected to return. The problem occurred when the patient was transferred from internal medicine to radiology, and

then to surgery. The bed control system was updated, but the pharmacy system was not. As a result, the pharmacy continued to send drugs to the old bed, which was by now occupied by a new patient. In this particular case the error was discovered.

Programming errors tend to lead to false data reporting, or system breakdown. In a system prone to errors, the staff often checks strange results. There are more problems with a system that runs so well the users stop challenging potential errors. Cleaning up a program can result in a less attentive staff.

SPECIAL PROBLEMS IN MEDICAL INFORMATION SYSTEMS

Since writing that article I have had more experience working directly with medical information personnel. I spent 1984 on sabbatical, first at the Massachusetts Institute of Technology and later at The Center for Medical Computing Science at the University of Frankfurt. It is possible that potential problems are even more severe than first believed, primarily due to the nature and method of software development and use, and to the changing role of information in the medical system.

Certain systems by their distribution and inherent nature are the most likely to be involved in litigation. These include patient record systems and treatment support systems such as nursing orders and pharmacy. These are generally referred to as medical information systems. The most important current developments are going on in the area of expert systems. These systems are very new. Ten years ago even the most advanced university medical centers were only beginning to install medical information systems.

Several developments in information systems have changed this environment. The development of faster, less expensive, general purpose machines has led to an explosive growth in the number of computers. Network and communications software allows those computers to be connected together in a wide variety of different combinations. Special languages, such as MUMPS, the Massachusetts Utility Multi-Programming System, were developed to serve the medical community. Information systems were pioneered in research oriented university medical centers, in part because of the need for research data. Military and Veterans Administration hospitals are currently implementing their systems. The great bulk of conventional hospitals do not yet have systems, however, the pressure to install them is accelerating.

A new profession has also arisen. Most traditional data processing managers were trained in business or accounting. In the medical area they have shown a limited ability to create systems which support patient care. Instead the pioneers of clinical information systems were computer scientists and

physicians with computer science backgrounds. There is now an American College of Medical Informatics, almost exclusively composed of physicians and computer specialists. The German term "INFORMATIKER" can be used to describe these professionals. They are oriented towards the automation of patient data and the changes in medical care which can result from that automation. It is this group which is causing the revolution in the use of computers in medicine and the one least known to the legal community. Informatikers believe that transmission and use of medical information fundamentally changes the concept of medical care. Medical records, which used to be the physician's notes of his personal knowledge, now become the chart of the patient's entire life. Access to this information allows the members of the health care industry to provide care in totally different systems. Second opinions, monitoring of health care, referrals, consultations, and transfers of patient from provider to provider come to rely on the information system. Informatikers see medicine as critically dependent on the movement and flow of information. To them, information is a positive good. Their ultimate goal is a sophisticated information system which can handle most or all of the physician's tasks.

Virtually all existing medical information systems are hospital based. This means that medical information systems are directly connected to the fundamental changes now occurring in American Hospitals. Hospitals used to be the workshops for individual physicians; increasingly they are becoming the direct provider and decision maker in medical care.

The development of the diagnosis related group system has caused a fundamental change in the system of paying for medical care and created a new demand on the medical information system. Under prospective patient reimbursement rules, administrators now need real time information on patients currently in the hospital, how they are being treated, and how much that treatment costs. The medical information systems are crucial to this effort. Hospital administrators use them to determine which physicians use the most resources. Auditors use them to control reimbursement. Competing demands can lead to system overload. The need for new types of systems has created extraordinary potential for significant legal problems. Problems with medical information systems do not just happen. They are caused by dramatically different perspectives on the key priorities of the medical system.

There are three important groups in a hospital working with a medical information system: administrators, physicians, and informatikers. Each sees the system as something different. The physician sees it as a helper, a new type of nurse or clerk who will provide information and carry out orders without changing the physician's fundamental control over the system. The administrator sees it as a control system. He can control the

physicians because he now knows what they are doing. The informatiker sees the system as the centerpiece of health care, allowing physicians and other professionals to be "plugged in" as needed. The informatiker likes bigger, better, faster and more complete systems.

All of the participants are oriented towards their own goals for the system. The system is more than a distributor of information. The reality is that information is a new center of power. Normally the physicians have power based on professional authority, and the administrators have power based on financial control. Both of these groups can use their power in obvious fashions. The informatikers power is control over the medical information system, but to get the system up and running, the informatiker needs cooperation from both of the other groups.

As a result, the informatiker must tell different things to different people. To the physician, he promises a helper who will serve the physicians´ interests. Therefore the informatiker first develops subordinate systems, such as clinical lab, nursing, bed assignment, and reporting systems. These systems do all the paperwork which physicians normally detest. What the informatiker knows, but the physician does not always realize is that the same information is the source of control for the administration. The informatiker must keep this secret until the system is installed, or the physicians will oppose the system installation. These conflicts in internal goals are rarely brought to the lawyer´s attention.

Despite the rapid reduction in the cost of computer hardware, computer power remains a scarce resource. Therefore someone has to allocate access to the information system, and determine what information is kept, and in what form. It is in these resource allocation decisions that the potential for malpractice is the highest. The pressure from the various interest groups can lead to compromises with severe unintended results. Two examples of typical problem areas are given in the appendix.

Liability standards will take a substantial time to develop. One major area of concern is liability for failure to use a computer system. I think this type of liability could arise in fundamentally different ways. The first would be to fail to use a computer system to check on specific problems which can be found in standardized medical databases, such as drug-drug interactions, or the latest contraindications to various types of therapy. The other area is the ordinary failure to maintain accurate patient records of the type which a computer system could provide. Allergies, patient histories and prior complications are all easily stored in computers, but can take substantial time to recall in a manual system. Automated medical information systems are clearly the state of the art, and without

them a hospital or doctor would be vulnerable under the leading case of the T.J. HOOPER.

To sum up the liability exposure, the problem is real and immediate. Short of passing a general products liability bill, which I do not suggest, the most direct effect this committee can have on the liability issue is in its instructions and oversight to the Food and Drug administration regarding the regulation of medical computer systems as devices. The liability and regulatory issues are intertwined because both legal concepts serve the same conflicting goals; how do we promote the advancement of medical technology while maintaining the maximum of patient protection, both physical and financial?

The primary question in both areas is what legal approach should be used to control clinical software? I am not persuaded that the current Food and Drug Act actually covers software. But I am confident that the product oriented approach of that act would be both ineffective and hostile to the development of the technology. The legal system should not attempt to define in advance what direction this technology will take. However, the liability and regulatory policies should be coordinated.

There are certain basic principles which should control all legal efforts in this area. First is protection of patients from the unreasonable risk of injury. Second, there should be a search for relative improvement in medical care, not absolute perfection. Third, any system should avoid entrenching existing institutions, whether governmental, industrial or professional. Fourth, in any implementation of a computer system there must be a financially responsible party. Fifth, in terms of patient therapy there must be a party clearly responsible for the proper operation of the system.

Compliance with these principles is difficult under the current legal system. Under the current regulation of medical devices and drugs, the federal government controls the manufacture and labelling of devices and drugs, and the states control the use. The division is similar in products liability, where the producer is strictly liable, but the user is subject to a test of negligence. For all of the reasons I mentioned earlier, the technological development of this field has made this distinction obsolete. For example, a hospital worker sits down at a terminal. It makes no functional difference whether the computer is located in the same hospital, across the country, or in another country. Likewise, it makes no difference whether the system is produced in his hospital, or purchased on the outside. It is of no importance if the system is one of a kind or one of a group. Yet both the regulatory and liability systems fasten on these irrelevant distinctions to impose widely different levels of regulation and liability.

The primary policy choice for this committee is between the product oriented concept of the current medical device legislation act, and a user oriented regulatory approach suited to the nature of this technology.

The primary problem with the product oriented approach is that it tends to stifle all of the attributes which make computer software such an exciting technology. Product oriented regulation tends to limit developments in a field to those companies which are both adept at the technology and sophisticated in dealing with the regulatory authorities. We can get the medical equivalent of the Pentagon's $600.00 hammer because ingenuity in dealing with the regulator is the key business attribute.

Second, product regulation tends to centralize production in a small number of firms. The first handful of firms approved can divide up the market. Regulatory approval is a substantial entry barrier. There are only a small number of viable hardware producers in the computer field, compared to the vast number of software houses. This is due to the different economies of scale in starting up operations. The regulatory burden could be crippling to small, innovative companies. It is precisely these innovative companies which are the strength of the computer field. Many of the most innovative producers are universities and hospitals. There is a tradition of sharing breakthroughs and software which could disappear if regulated.

Third, regulation of the software tends to limit the flexibility of the user in adapting the device to local conditions. While the food and drug act provides for customization of the device to a patient, it does not provide for customization to the institution, which is often critical in clinical software. Modifications of systems by producers in light of system failures or increased knowledge would be slowed by the need for regulatory approval.

Fourth, under the current concept, liability for defective software is diffuse. Small companies may not be financially viable. Insurance in this area is becoming unobtainable. The liability exposure is determined by traditional strict liability with contractual disclaimer and indemnity.

Fifth, some software will be exempt from regulation, because it is created by the using hospital. Software can also disappear from the regulatory system because of the demise of the producing company, while the software is still in use.

These deficiencies can best be addressed by recognizing that software is a fundamentally different item from a scalpel or an x-ray machine. Perhaps when software is distributed in a mass market setting such as Wordstar or Lotus 1-2-3, product oriented

regulation would be appropriate. I do not suggest ignoring the potential risk. My proposal is instead to adopt a regulatory system oriented towards the user of the software, rather than the producer, and fix the liability for defective software at the same point. Such a propósal would involve registration of each user location.

This proposal would 1) focus regulation on the parties actually controlling the use of the software. It would clarify responsibility for control of the software and the potential uses to which software would be put. 2) Liability would be strictly imposed on the using hospital, as the place best able to evaluate what level of oversight is needed. By concentrating liability at the user level there would be an increase in competition, rather than a reduction, since the financial viability of the producer would no longer be an issue. 3) The users are already subject to regulatory control. They are familiar with the requirements of the regulatory authorities.

I am not suggesting that medical software be exempt from either regulation or liability. However, in the case of this unique product, the public interest would be best served by imposition of strict liability at the level of the user, combined with a modest level of regulation on the same party. This combination would provide the optimum mix of protection of consumers with minimum restrictions on the development of this revolutionary technology.

APPENDIX

Two discrete situations which exist at the opposite ends of the medical information environment provide excellent examples of potential problems.

The first problem is the accuracy, timeliness, useability and friendliness of the medical information. In this area all three groups have the same goal of providing accurate information. However, the groups differ in what information is needed. Administrators want the information that allows financial control. Physicians normally want the information needed for their next decision. Informatikers want systems which run smoothly, don´t overload, and don´t break down. Problems can crop up in the most trivial way, but with potentially severe consequences.

In one information system, every tongue depressor and aspirin was in the information system, but management had determined that there was no room for blood pressure measurement or other patient data. In another system the pathology laboratory saved the fact of every test, but not the result. Possibly these two converted billing systems fall outside the

arena of patient information systems, but when access to unimportant data is available by computer, while vital data is kept by hand, serious questions can be raised concerning the standard of care at the institution.

At one major development center for medical information systems, the system designers allowed any system user to send the only copy of the patient's chart to any room in the hospital. There was no provision for verification of arrival, or insuring its return to the record room. When it was suggested that the loss of the Hospital's only copy of what it did to a patient could involve substantial liability consequences, the suggestion was met with disbelief.

Additional problems arise from the ease with which computerized medical records can be altered without a trace. Backup tapes can be used to archive the state of the data at a particular time, but they must be protected. However it is very time consuming to search for this type of information, especially on tape.

The single advantage in dealing with the problem of info mation accuracy is that no one really wants bad data. It is essentially a management problem, but it may be up to the counsel to inform the management they have a problem.

The second problem is protecting the patient's interest in the privacy of medical data. Patients have normally expected that their medical data was kept secret. In the past this was true more because of the difficulty of locating, copying and interpreting the data than any great investment in privacy. Unlike the accuracy of the data, all of the groups which work with data have some reason to be against true data privacy. To the administrator, data privacy means less control. To confront the physician on issues of cost, he needs all the information the physician has, and he needs to be able to distribute it freely . To the physician, data privacy means the computer is less useful; it is harder to give orders from the office or to check on a patient from home. To the informatiker, data privacy means a clumsy system which cannot be easily connected to other systems.

For all groups, data protection costs money which could otherwise be spent on something else. So it is typical to do what the law requires, but no more. As the technology develops, it becomes easier and easier to evade the spirit of the law, while staying within its boundaries. In many cases there are no statutes whatever, which leads the hospital to conclude that there are no legal checks on its actions. There is often no appreciation of common law rights of privacy.

At one of the nation's most distinguished medical centers, there is a development center for medical computing. The

hospital has 64 different computer systems. Most are virtually unprotected, but one system is password protected and encoded. That is the physician's salary system. Other hospitals seem insensitive to the need for confidentiality of data. Computer systems staff routinely have access to all patient data, and top administrators treat patient data as a corporate asset, subject to their control. Researchers at major medical centers expect virtually unlimited access to patient data.

The problem is that the potential liability exposure arises from a legal requirement which is not a high priority item for achieving each group's own internal goals. Even where there are extensive statutory requirements, such as government systems subject to the Privacy Act, protection is almost nonexistent. In a presentation to 70 Veterans Administration programmers and system managers last year at a conference, not a single one had heard of the Privacy Act or thought it had anything to do with their operations.

In all of these cases there is a common thread. There had been a complete breakdown in communication between the legal staff, who had no idea what was going on, and the technical people who design and operate the systems. It is this breakdown which is so critical. The medical area has more than its share of prima donnas, who resent any outside investigation of their domains. Computer systems staff tend to think of the machines as theirs, and that they should control who gets what information. Administrators tend to think of hospitals as a business, where people at the top can have any information they want. Physicians want to get on with treating patients, and have a horror of people looking over their shoulder. All professions had their origin in the exclusive control of information by a small group. Technological change has deemphasized the expert's role as the mere accumulator of information, and emphasized the role of decision maker. The information systems which support or replace the decision maker must be held to the highest possible standard of care.

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WRITTEN TESTIMONY OF PROF. VINCENT BRANNIGAN TO THE HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY MARCH 18, 1986
Part II

MEDICAL INFORMATICS AND THE REGULATION OF DECISION MAKING: THE CHALLENGE OF A NEW TECHNOLOGY

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The introduction of medical information systems has not yet changed the legal structure of health care. However the development of systems that can challenge all or part of the physician's medical judgment will require changes in the definition of the practice of medicine. Such changes must take into account both the rationale for regulation and the potentials of modern information systems.

1. INTRODUCTION

Under the existing structure for the regulation of health care, physicians have an effective monopoly on primary medical decision making. Physicians have jealously guarded their control over the system.[1] Recent developments in computerized record keeping and decision making have the possibility of providing both closer control over physician decision making and possible automated substitutes for physician decision making. The introduction of medical informatics requires a focus on the legal requirements of the practice of medicine, and examination of alternative systems employing medical information systems.

For the purpose of this article "medical decision making" is the process of diagnosing and determining the appropriate treatment for diseases. Decision making must be distinguished from the technique of treatment, however skilled.

2. CURRENT CONTROL STRUCTURE

2.1. Professional Autonomy

The hallmark of medical decision making in the U.S. is professional autonomy. Individual physicians make decisions on types of treatment with little or no prospective review and only modest retrospective review. In addition, physicians control the vast majority of all health care delivery either directly or indirectly. The role of government is distinctly limited. Its supervision over physicians is effectively limited to the licensing exams, which are administered largely to graduates of accredited American medical schools. Direct quality reviews of

physicians are rare. What little review takes place is normally not directed to patient care, but to reimbursement and is conducted primarily by insurance companies. Physicians therefore have an extremely favored status in the law. The legal system limits competition while affirmatively conducting very few reviews of physician activity.

2.2. Social Control

The justification for professional autonomy is normally a demonstrated superiority of the professional decision making process. Decision making is the heart of any profession. All professions would prefer to be self defining, with the profession determining what is a professional decision. However, because of the need for the legal system to police infringements on the professional sphere, the legal system sets the limitations on the autonomy of professional decision makers. For example, the legal system decides what is the practice of medicine, dentistry, or law. Determination of the boundaries of professional decision making is not static; it changes with social needs, political power, economic development and technological innovation. One of the most dramatic shifts possible in any profession occurs when a determination is made that professional judgment is no longer needed in any given decision. For example, the movement of a pharmaceutical from prescription to non-prescription status is an indication of the limited need for professional judgment.

In our society, the determination that a professional decision is no longer required tends to be made by regulatory authorities as a question of social policy. The social question relates to the particular risks a society wishes to run. For example, aspirin is universally available in the United States, but can only be sold in pharmacies in Germany. On the other hand, many remedies promoted in Germany by the "heilpraktiker" practitioners and pharmacies would be banned as quackery by the Food and Drug Administration and the American Medical Association.[2] The scope of professional judgment is a matter of social, and therefore legal policy.[3]

The legal structure of the practice of medicine arose in the early part of this century at a particular stage of medical technology. The development of "scientific medicine" gave the medical practitioners a tremendous tool to exclude the lay public from medical decision making. The authority of the physician was based not on professional privilege, or the arcane nature of the knowledge, but on the demonstrably superior results of the scientific practitioners.[4]

2.3. Effect of the Regulatory Structure

In the face of this superiority there were dramatic changes in the structure of medical care. Some alternative therapies were considered useless, others dangerous. Many medical schools were

closed, and the remaining schools developed a rigid academic structure. Specialization developed, and specialists adopted the principle that no one outside a given specialty could judge the work of the specialist.[5]

The medical staff of the hospital, a group of peer-competitors, became the key review system to determine which other practitioners would have access to the hospital, and which therapies were effective. Despite the term "staff", the physicians were private practitioners, not employees. Through the organization of the medical staff, private practitioners were able to use the hospital's facilities without fear of outside review.[6] There is some evidence that accurate medical records were a by-product of the development of the medical staff.[7] Without accurate records, there was no way to perform the quality control which justified the otherwise anti-competitive conduct. Staffs were often closed to competitors, and alternative practitioners, such as midwives, were barred from the premises.[8]

The legal system, for the most part supported this development.[9] All states adopted licensing rules, with administration and control largely in the hands of the medical profession. Competition among physicians was suppressed by limitations on advertising.[10] Staffing regulations were developed to exclude licensed physicians of competing schools of thought from practicing in municipal hospitals.[11] The locality rule in medical malpractice gave a tremendous boost to local medical societies, by allowing them to control the local standard of care.[12] Special product liability doctrines emphasized the preeminence of the physician by limiting the manufacturer's duty to warn. The physician was a "learned intermediary" who made decisions for the passive patient.[13]

Even the most private decisions, such as abortion, were not left to the individual but required a physician's approval. In the landmark case of Roe v. Wade the Supreme Court declared this most personal of decisions to be a medical decision decided by the physician, rather than a personal decision by the patient:

"This means, on the other hand, that, for the period of pregnancy prior to this "compelling" point, the attending physician, in consultation with his patient, is free to determine, without regulation by the state, that, in his medical judgment, the patient's pregnancy should be terminated . . . .To summarize and to repeat: . . . For the stage prior to approximately the end of the first trimester, the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician."[14]

This remarkable passage indicates the high point of legal deference to physician decision making. The court was willing to

say, as a matter of constitutional law, that a decision that was so private that it could not be regulated by the state, could not be made by the woman herself, but was a "medical judgment" for the physician.

This decision is indicative of the power accorded to physicians in the social structure of health care. Only the individual physician knew the patient's needs and conditions. Only the physician could make the difficult decisions necessary to treat the condition. Only physicians of the same locale, school of medical thought and specialty could question the decision of the treating physician. Finally, any challenge to the physician's decision took place after the fact, not during treatment. Physicians have come to accept this current situation as permanent. However, the development of medical information systems threatens the underpinnings of the entire physician centered system of medical decision making.

3. USE OF COMPUTERS IN MEDICAL DECISION MAKING

3.1. System Capabilities

Medical decision making is essentially an information based technology. It has an enormous potential for use of computer systems. Computers can store vast quantities of medical knowledge. They can sort, retrieve and analyze that data in novel ways, and can increasingly do it in real time, prior to key decision points. Computers can also perform a number of complex diagnostic techniques. Virtually all the modern imaging technology in medicine, CAT (computerized axial tomography), NMR (nuclear magnetic resonance), and ultrasound scanning, depend on computers to produce the image. This means that automated information is available directly to an information system, which may be able to directly process the result. Computers can monitor vital signs on a continuous basis and administer drugs in a controlled manner. Laboratory testing in many clinical pathology laboratories is fully automated.

3.2. Effect on Physician Control

These advances, though significant, would not threaten physician control of the health care system. Physicians have long used technicians and assistants to extend the physician's reach. Physicians have benefitted financially and organizationally from controlling an ever larger number of assistants and machines. Physicians have controlled the system because the regulatory system accepted the superiority of their medical decision making.

Medical decision making can now be examined and challenged in a way never before possible. The development of information systems both allows sophisticated analysis of medical judgment and the creation of "expert" systems that simulate or replace that

judgment. The ultimate effect of the automation of medical decision making will be to clarify the nature of medical judgment itself. Computers are relentless in stripping away the mystique of professional skill, when no real judgment is involved.

The threat to physician control comes if the computer can actually compete with the physician in judgment. Physicians resist this idea. The physician thinks of professional judgment as something uniquely human and professional. When all else in medicine is being done by machine or technicians, the physician expects to maintain control because of the superiority of professional judgment.

3.3. Medical Judgment

Physicians sometimes assert that automation of medical decision making is impossible, because there is some "judgmental" factor beyond machine understanding. Interestingly enough, this is an argument for more, not less control over physician decision making. Assume that some physicians are better decision makers than others, for reasons which we cannot currently determine, but the superiority of their decision making is demonstrable. In a rational society, such decision makers should specialize in decision making, and other physicians, perhaps more skilled in technique, should be required to submit to the decisions of the specialized decision makers.

The obvious first use of computers is to identify these superior physicians. By collecting and comparing the treatments and outcomes on a wide variety of patients, it will be possible to develop and maintain norms for treatment. Physicians will be called upon to explain patient outcomes that deviate from the normal range. Due to the vast quantity of data to be analyzed, the speed with which records must be accessed, and the need for accurate statistical information concerning the effectiveness of various therapies, such comparisons would be impossible without computerized medical information systems.

The next stage is to directly intervene in clinical care. Computer systems allow monitoring on a "real-time", continuous basis. Instead of post hoc case review by peers in the medical staff, the information system can check any decision against the established norms prior to treatment and query the physician to explain any deviation. The system can be programmed to act as a "second opinion," require a consultation, forbid the use of resources to carry out the procedure, or simply note a caution for the record.[15] The physician will be constantly required to prove that his medical decision making is superior to that of the information system. If a given physician is demonstrably inferior to the computer generated norm, he will be replaced by another physician who is superior, or possibly even by the machine itself. Like the legendary John Henry, who challenged the steam drill, the physician will be forced to justify his

superior decision making capability on a continuous basis.

3.4. Substitution of Computerized Decision Making

A final step would be to use and rely on the computerized system in place of the physician. Such replacements have happened in some other technical areas. Stationary engineers were once required for all steam plants. They have been replaced by servo mechanisms. Inertial navigators guide submarines. The replacement of physicians by computers would involve complex problems. Perhaps the most important is whether the physicians will control such systems.

Some tasks are beyond computers at the current stage of development. Computers can control the heating, air conditioning and other services of a skyscraper, but they cannot change light bulbs. Because some tasks are beyond any computer system, physicians assume that any computer system will be their subordinate. This is simply not true. No matter how complex the task, it is the decision to initiate the task which determines control over the system. Physicians cannot perform kidney dialysis, only machines can. Proper analysis of the potential and limitation of medical information systems will require an in-depth analysis of medical decision making, with particular attention to the portions which can be performed by computers. In addition computers have capabilities not only to model the human decision making process, but to use completely different decision methods and rules to arrive at the same result. It is possible that the process of ordering the medical knowledge into a form that is usable by computer systems is the critical step in determining whether legal restrictions on who can practice medicine will apply.

3.5. Knowledge Engineering

Computer systems run most efficiently on formalized knowledge structures. Knowledge engineering takes the inchoate mass of data in a field and structures it. Relationships between individual units of data are developed, and suitable decision rules are derived from the information. This process lays the groundwork for advanced decision making, either by human specialists, or computer based artificial intelligence systems.[16]

Knowledge engineering can cause a radical shift in the interaction of professionals with the informational component of their work. Knowledge engineering tends to clarify the decisions made by professionals, by indicating those areas where a given set of facts leads to a single unambiguous conclusion, or a given set of probabilities. In such an area, the professional is merely a repository for knowledge, not a decision maker.

Consequently, formalization of the knowledge in a field can lead to dramatic changes in the scope of professional decision making.

4. LEGAL STRUCTURE OF MEDICAL DECISION MAKING

The ultimate argument by physicians to control the medical information system is to assert that they are the persons licensed by the state to perform medical decision making, and therefore such decision making must be subordinate to their professional authority. Such reasoning fails to take into account the rationale for such authority and the possibility for change.

Under most state licensing laws, only physicians can "practice medicine". The statues are typically written in very broad form, with the practice of medicine defined as diagnosing and treating disease. Traditionally the regulation of medical care is part of the police power of the state, the general power to regulate the health welfare and safety of the people. As such, it is a broad power which is limited only by certain narrow constitutional doctrines. However, the driving force for the autonomy of the physicians was a determination that they provided better decision making. In those areas where that was not so clear, legislatures have been willing to override medical decision making.

One of the most dramatic changes has been in the area of informed consent. This concept, which grew out of medical malpractice law, has as its foundation the concept that the patient is the key decision maker, not the physician, and that the physician has an obligation to put in the hands of the patient the needed information for deciding at least the general strategy of the medical treatment. Importantly, informed consent is oriented towards the dignity and personal autonomy of the patient, not the superiority of the patient's decision making. [17]

A second area in which the control system of the state has been limited is in the conflict between state regulation and the First Amendment. The application of at least a limited right of freedom of speech has allowed doctors to truthfully advertise their qualifications and therapies.

An attempt to expand the right of privacy to cover the physician/patient choice of therapy was rejected by the Supreme Court in the area of laetrile, a purported cancer cure. A suggestion that patient autonomy defined a right to use whatever medical therapies the patient desired was rejected by the court.

Finally, despite the sweeping language of the medical practice statutes, it is clear that physicians do not have a monopoly on all diagnosis and treatment. Over the counter drugs and diagnostic tests are dispensed to patients, normally on the basis that patients can understand the use of such drugs. Legislators

usually have no particular interest in preserving professional monopolies as such.

5. RATIONALE FOR CHANGES IN LEGAL RULES

There is no exact formula for determining whether a particular legal rule will change due to technological development. The legal system responds to a wide variety of political and social forces. However, some of the better arguments can be derived from past conflicts. Some factors which would tend to convince legislators to deregulate medical decision making would include:

5.1 Personal Autonomy of the Patient

Our society has made a direct commitment to patients that they will have control over the medical treatment they are subjected to.

5.2. High Level of Medical Certainty

When there is no great dispute that a particular combination of symptoms leads to a specific diagnosis or treatment, there is little need for the "judgment" of the physician.

5.3. An Acceptable Level of Risk of Error.

Our society does not expect perfection, but any system would have to be at least as reliable as a qualified physician.

5.4. Cost/benefit Improvement

To challenge the inertia present in any regulated area either true cost savings or improved service must be demonstrated.

5.5. Acceptable Alternative Regulation

Some method for acceptable premarket clearance for any such system would have to be developed. This does not necessarily mean government regulation. Private approval by accepted testing labs might be accepted.

5.6. Financial Responsibility

Appropriate structures would have to be developed for the financial consequences of mistakes in the system.

6. CONCLUSION

It is clear that in the industrial revolution we have accepted that machines are normally better than men at manual labor. The information revolution exposes those parts of professional judgment which are simply "intellectual factory work". Unless

the physician can continue to improve his decision process it is possible the physician will become a type of auxiliary to the medical information system. The physician will carry out the technique of surgery or other therapy, but will not make the fundamental medical decisions. This technical transformation will require appropriate legal response.

NOTES AND REFERENCES

[1] Feldstein, Political Environment of Regulation in REGULATING HEALTH CARE, THE STRUGGLE FOR CONTROL 9 (Levin, A., ed. 1980).

[2] The word "Heilpraktiker" defies translation but represents the practice of botanical healing, perhaps similar to naturopathy.

[3] FELDSTEIN, supra note 1

[4] P.STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 144(1982).

[5] STARR, supra note 4, at 223-225,355-359.

[6] M.I.ROEMER & J.W.FRIEDMAN, DOCTORS IN HOSPITALS: MEDICAL STAFF ORGANIZATION AND HOSPITAL PERFORMANCE (1971).

[7] MALCOM T. MacEACHERN, HOSPITAL ORGANIZATION AND MANAGEMENT, at 600 (1946).

[8] STARR, supra note 5, at 198-232.

[9] Pollard, Fostering Competition in Health Care, in REGULATING HEALTH CARE, THE STRUGGLE FOR CONTROL 164 (A. Levin, ed. 1980).

[10] Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976)

[11] Hayman v. City of Galveston, 273 U.S.414 (1927), (exclusion of osteopaths from the medical staff of a municipal hospital)

[12] STARR, supra note 5, at 111.

[13] (Learned Intermediary) Mahr v. G.D. Serle & Co., 28 Ill.Dec. 624, 390 N.E.2d 1214, 72 Ill. App. 3d 540 (1979), Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 577 P. 2d 975 (1978).

[14] Roe v. Wade, 410 U.S. 113,163 (1973).

[15] The COSTAR (COmputer Stored Ambulatory Record) system has this capacity. Barnett, Winikoff, Dorsey, Morgan & Lurie "Quality Assurance Through Automated Monitoring and Concurrent Feedback

Using a Computer Based Medical Information System" 16 MEDICAL CARE 962-969 (1978) The COSTAR system checks for the presence of Beta hemolytic Streptococcus infection and whether appropriate antibiotics were ordered. The system is described as concurrent because the audit takes place while the patient can still be effectively treated. The system has been extended to hypertension, urinary tract infections, pre-natal care, and influenza vaccinations.

[16] Feigenbaum,E.A., Knowledge Engineering: The Applied Side of Artificial Intelligence in COMPUTER CULTURE: THE SCIENTIFIC, INTELLECTUAL AND SOCIAL IMPACT OF THE COMPUTER (H.R. Pagels, ed. 1984).

[17] Schloendorff v. Society of New York Hospital 211 N.Y. 125, 105 N.E. 92 (1914)

[18] See Note 10 supra

[19] United States v. Rutherford 442 U.S. 544 (1979)

This paper has been submitted to the Fourth World Congress on Medical Informatics Copyright (1986) Vincent Brannigan, College Park MD

Mr. VOLKMER. Thank you.

Before I go to Dr. McDonald, I forgot to ask all three of the previous—and they're still here, so I'd ask them—the previous panel—to answer this question. The question is, have any of you been ever asked to serve on any of the advisory panels to the FDA?

Dr. Myers, have you?

Dr. MYERS. No, but I did some months ago have a telephone call from them to pick my brains. This was at the time they were first, as far as I could tell, beginning to think about what they should do, and in a broad sense they picked my brains.

Mr. VOLKMER. All right.

Dr. Gardner.

Dr. GARDNER. No.

Mr. VOLKMER. None.

Mr. Baker.

Mr. BAKER. No.

Mr. VOLKMER. All right. Thank you.

Excuse the interruption, Dr. McDonald.

Dr. MCDONALD. Thank you.

I'd like to just point out that although I am on the public relations committee for the American College of Medical Informatics, I was invited as a citizen to testify, and this is not necessarily the beliefs or views of the whole college.

Second, I'd like to correct, or at least modify a little bit, some of the implication maybe you drew from the written testimony, and that I don't think that the technology is too mature to use. I think it's too mature to standardize or regulate. I think it would be a little bit like when the Wright Brothers got out of their plane they said, "Okay, now we're going to set up the FAA, and you're not really qualified to fly this plane; get off."

They still used those planes back in those days, but there wasn't enough awareness; we didn't know the business; and I think this is a very, very, very young field, and I think there's a lot of romanticism and myths which are kind of being targeted for being fixed, and until we see how it evolves we don't know what needs to be fixed, and I guess I would say that the FDA's kind of approach to this is a testimony to the doggedness of organizations, and that even though it may not be possible, they're going to go ahead and do it. They'll try to do something. They'll come up with an answer, regulation, even though it may not really match any kind of really absolute reality.

One other background piece of information is that we talk about the expert as sort of the knowledge about the field as being the expertness, and it's sort of—that's the romantic part. We kind of think of medicine as being Sherlock Holmes. That's sort of the essence of medicine. But a whole lot of the medicine is gathering the facts. It's sort of the dog work before.

I'd like to make an analogy. We could automate an automobile to drive through a street; if the driver typed in, "There's a truck three feet ahead of me and"—you know, full details as he drove along specifying exactly what's there, the car could easily be programmed to get around all those vehicles if he gave the position, size, and location of those other objects, but that would be blatantly impossible because people couldn't spend the time typing in all this

stuff to get from A to Z, and the big part of the medical computing problem is getting all the facts about the patient [36] accessible to the computer.

With that background, let me go to my prepared statements. I'm going to try to answer all four questions that were explicitly asked: How should medical information systems be verified and regulated? Two, what should be done to assure timely re-certification of such systems? Three, who should be allowed to use such systems? Four, what should be done to protect confidentiality?

The first question, I think, begs a question, and that is, why regulate them at all? Some would answer, "because we're on the brink of a radical new kind of computing brought about by artificial intelligence techniques and that"—and this is the second one that's important—"existing legal, ethical, and marketing forces are not adequate to assure proper use of these systems."

A critical examination of the history of medical computing and the current realities of the research in artificial intelligence refutes this line of reasoning.

First the history. Artificial intelligence is not the only technique for doing intelligent things with computers. Computers have been doing intelligent things in medicine, using statistical decision theory, mathematical control theory, and plain old programming, for the last 15 or 20 years.

In 1964, Homer Warner [36a] published a landmark report about computer systems that could diagnose congenital heart disease with 90 percent accuracy. Dr. deDombal from Leeds, England,[36b] has used a similiar approach with excellent results in a diagnosis of the acute abdomen since the early 1970's. In the midseventies Howard Bleich [36c] and coworkers from Beth-Israel Hospital developed a very proficient consultant about acid-base disturbances; very accurate.[37] In the midseventies investigators at Massachusetts General Hospital; the University of Utah; my own institution, Indiana University; implemented rule-base systems that review patients' computer-stored records (and Dr. Reed described some of these) and remind physicians about a patient's condition needing attention. These are all built with plain old programming, no words or talk about artificial intelligence at those times.[38]

In clinical trials, we and others have shown that physicians increase their use of the intervention suggested—in our case it was preventive care—by a twofold to fourfold increase among eligible patients.

Interestingly, in our experience physicians only increased what they already meant to do. We didn't teach them to do anything new. The new kinds of things they refused to do. So it's kind of an activator rather than a convincer.

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[36] Dr. McDonald asked that "accessible" be changed to "into."

[36a] Dr. Homer Warner, M.D., Ph.D., is chairman of the Department of Medical Informatics, University of Utah, Salt Lake City, UT.

[36b] Francis T. deDombal, M.B., M.D., is a consultant with the Leeds (U.K.) Area Health Authority and Reader in Clinical Information at the University of Leeds.

[36c] Dr. Howard Bleich is codirector of the Center for Clinical Computing, Beth-Israel Hospital, Boston, MA.

[37] Dr. McDonald changed this to read, ". . . acid-base disturbances. It was very accurate."

[38] Dr. McDonald asked that the phrase ". . . no word . . . times." be deleted.

Diagnostic programs have been around since the midseventies. In fact, computer diagnosis with the electrocardiogram has been very successful, and this is a commercial venture that Dr. Baker didn't mention, because it's not tied to artificial intelligence, but is now employed in over 10 percent of all electrocardiograms analyzed in this country done by computer and very accurately.

Computer-controlled drug infusion machines are also quite successful. They can reach a target goal, such as normal blood pressure, much faster and with less overshoot than conventional manual methods. They use the same control theory that pilots use or computers use in 747's[38a] to land the planes, and that's how I understand[39] why we don't bounce so hard when we land on 747's like we do on the smaller ones.

In the absence of any relevant regulations, the medical profession has been very cautious and critical in the acceptance of this kind of intelligent computing. In fact, computers [physicians] have largely rejected the above-mentioned consulting programs because they required considerable physicians' time to input patient data. Physicians are excellent arbiters of time, and they'll do things that save them time and they'll not do things that cost them more[40] time.

Diagnostic programs that do not require human data input, such as the EKG [electrocardiograph] analyses, have been well accepted, and these have remarkable diagnostic accuracy, a 98- to 99-percent accuracy. However, the vast majority of these now commercially sold are sold with physician, human cardiologist, overreading. The computer puts it out, and the human double reads them. They start out with less of this, and it's almost gone to almost 100 percent, is what I am told.[41]

This highlights the cautiousness,[42] the existing cautiousness, of the profession. History therefore argues that malpractice concerns, ethical standards, and tradition impose substantial and conservative controls on the adaption of intelligent computer systems by medical professionals. This is certainly not an out-of-control situation that cries for external regulation.

In addition, though artificial intelligence has made and will continue to make important contributions to the field of medical computing, it's not a magic bullet that will rapidly solve the remaining barriers to intelligent computer systems in medical practice.

One barrier is the slow speed of the physician-computer interface. If the physician has to spend 20 minutes talking to the computer about his patient to do something he could do or get out of his consultant in a couple of minutes, he won't do it. [Use the computer.]

In addition, there are difficulties in transferring clinical data among computer systems, for example, from a laboratory system to a decision support system. These are really very difficult barriers

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[38a] Dr. McDonald changed this phrase to read "control theory that computers in use in 747s use . . ."

[39] Dr. McDonald asked that "how I understand" be deleted.

[40] Dr. McDonald requested deletion of the word "more."

[41] Dr. McDonald changed this sentence to read "They started out with less of this [overreading], and it's gone to almost 100 percent, I am told."

[42] Dr. McDonald requested deletion of the phrase "the cautiousness . . ."

which do require some standardization, and there are efforts now underway under the ASTM [American Society for Testing and Materials] Subcommittee [to develop such standards] and the AMA has been involved in that.

In addition, there is substantial ignorance about what physicians are really doing when they decide and where in the process computer support will be most helpful.

Finally—and this may be antireligious—there is a genuine dearth of empirical data on which to base detailed rules about care for patients. We pat ourselves on the back, we in the medical profession, for all the progress we've made in the past 50 years, but we're still looking through a mirror very darkly—very, very darkly; and I don't think in terms of the medical knowledge[43] of what diseases are that we don't know more than 5 or 10 percent of what we need to know to take care of patients. *Legionella* is not a new disease. It was around since at least the early 1900's. We just didn't know about it. We called them [the cases of *Legionella*] all pneumonias.

Considerable research, such as that supported by the National Center for Health Services Research and the National Library of Medicine, are required to solve at least the informational problems I've described above.

Hype also surrounds discussions of artificial intelligence, and Walter—and I'm not sure I'll be able to spell this right—Metiscela from TRW (TRW is one of the most experienced large programming project companies, and they're one of the few that are able to stay very reliably within their estimation of time and materials to finish programming projects) has found that AI offers no more reasoning capability than conventional computer algorithms and that humans are required when reasoning is needed, particularly for unexpected events. I would submit that physicians or some other bright human is going to be required to oversee what computers do on complex diagnostic decision processes, though they may find very, very helpful the outputs from various systems and support programs.[44]

In this context, the notion that physicians will turn to a computer's advice exactly as they would turn to a human consultant, I think, is science fiction, and this is discussed in more detail in the written testimony.

In short, I think there's no current need for standards or regulations in medical computer software whose outputs are interpreted by a medical professional. Wrong or out-of-date textbook information has the same potential to misdirect the physician, yet we haven't tried to standardize or regulate textbooks.

The history of medical computing suggests an existing strong critical and conservative process in the acceptance and adaption of such systems. The field is still in its infancy, so it's much too early to talk about what's really needed and what to regulate. Further, any regulation is only likely to stifle the development of this one

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[43] Dr. McDonald asked that this be changed to read ". . . very, very darkly . . . In terms of . . ."

[44] Dr. McDonald altered this sentence to read ". . . though they may find the outputs from various systems and support programs very, very helpful."

technology which I think is going to be a Godsend to cost savings, (to answer an earlier question in terms of efficiency). The medical field is way behind most industries in the use of information systems to improve efficiency in their process.

Regarding the second question, regarding how often databases should be updated, this, I think, should be answered by those who use the systems. Remember that physicians have had 9 to 15 years of post-high-school education in biology and medical sciences. They're well aware of the limitation of their informational sources and have always operated accordingly.

Market forces have been adequate to determine the frequency of updating of classical medical textbooks. There's no reason to expect that similar forces will not operate efficiently on computer support systems.

Questions about what kind of individuals should be allowed to use these is a difficult one. It certainly would be appropriate to prohibit commercial use of such systems by nonmedical professionals. On the other hand, although I say this with trepidation, I think it would be arrogant and presumptuous to legislate against the use of such systems by ordinary individuals for their own curiosity or interest. Certainly they go to the medical library and they read medical textbooks, and I think the worst that's going to happen is we're going to have an enormous outbreak of the sophomore medical student syndrome.

Whenever the medical students read a chapter on Hodgkins' disease, the incidence of Hodgkins' disease, at least visits for Hodgkins' disease, goes up about 30 percent in the local practice organizations. I had it myself once—twice—in medical school. And the problem is, you can't interpret the findings in the context of how bad, and how serious, and how likely, and how often, and all these other kind of things.

We can be sure that some individual will use and acquire such systems, but the consequences shouldn't be substantially worse than lay interest in medical textbooks and journals intended exclusively for physicians.

A last question deals with confidentiality. Clearly it's important that medical information remain confidential, and technical means are available to provide almost any level of confidentiality required. In fact, there's been a recent Federal report detailing all the range of security appropriate to various kinds of computer systems.

Now the most extreme forms require large passwords, like 10 or 15 typed characters, changed each day, so you have to memorize a new one each day; narrow restriction of access by passwords, so you only get certain limited kinds of information; and special shielding of rooms containing CRT's and computers to prevent monitoring by microwave snoopers. This [microwave snoopers] is apparently a fairly easy technology, that you can see[45] the signal coming on the CRT by pointing devices at it. They [the standards] also require encryption of all stored information and elimination of any dial-up lines.

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[45] Dr. McDonald changes this to read ". . . that lets you see . . ."

But when trying to decide about security, we have to consider the costs. Obviously there are dollar costs. Security keycard readers on every terminal could easily add 20 to 30 percent to the total cost of hospital information systems, in which you are now talking in terms of 500 or more terminals. The cost of protective shielding to prevent microwave snooping could be prohibitive. I mean, you might have to shield the whole hospital and all the buildings and all the rooms.

There are other costs, and the most difficult problems—and these are really the opportunity costs—the most difficult problems physicians face taking care of acutely ill patients is obtaining past information about the patient. I remember too well the hours it could take to obtain a hospital chart when I was an intern at Boston City Hospital. Today, a large chunk of every physician's day is spent finding, organizing, and assimilating information about individual patients.

What we really need is faster and easier access to medical information, particularly if we're going to make medical care less costly. Yet the security protection we place on medical systems—the more we place on it, the more difficult it can be to obtain the data, and even small barriers can make such systems very difficult to use by physicians.

I don't think this is just a matter of politics, of what they'd prefer, but just the daily operational realities. A physician may practice in three or four different hospitals and have only an occasional patient admitted to any one of them. Thus, he may forget his access code. How does he take care of his patient that day?

If security allows him access to only his own patients, how will he take care of [patients] when he is cross-covering for his partner who's off sick or suddenly had to leave town? If a patient suffers a cardiac arrest now, how do I take care of the patient in that room who I have no access to? How am I going to find out what drugs he's on?

If security is so tight that it interferes with daily operational realities, the reality is that people subvert it, and in fact in those hospitals that have very, very tight security, what you'll often see is the general password written on the terminal. You know, they have all the limited, limited, limited, but that kind of takes care of it so people can take care of their problems.[46]

So some level of security is required. At a minimum, access to programs that can search across patient records and display identifying information should be very, very tightly protected. Tight control should also be applied to terminals that are not in patient care areas. I submit the physical location will tend to prevent access by outsiders in patient care areas just as it does for the manual chart.

We don't believe it's practical to limit medical or nursing staff access to only their patients because of the problems of cross-coverage, rotations, and emergencies. Institutions should have some way of limiting access to medical data about VIP's or other individuals who may be under special threat of snooping. Similarly, the capa-

[46] Dr. McDonald changed this to read "You know, they have all been limited, limited, limited, but they take care of it so that people can solve their problems."

bility of restricting access to certain kinds of data, such as venereal disease, might be desirable.

But we really don't know what the costs are, the values of this data is; there really isn't much idea about what the risks are from all this snooping that we worry about. It would be much easier to determine the level of security required if we had measures of the real threat. How often do unauthorized personnel try to access medical records and manual systems? How much could it be worth to them? Does anyone know?

Billing records contain diagnosis and procedures, and laboratory results are transmitted between hospitals and Blue Cross insurance companies across the country over the regular telephone with no special protection. Current operational procedures—this suggests the medical privacy threats are not large, but I think we need some studies, or better understanding, or estimates of what they really are.

Thank you.

[The prepared statement of Dr. McDonald follows:]

The Subcommittee on Investigations and Oversight of the Committee on Science and Technology, March 18, 1986.

Written Statement by Clement J. McDonald, M.D.

I am a University Professor at the Indiana University School of Medicine. I have been developing and studying medical information systems, part time since 1964 and as my major research interest since 1972. I practice medicine and take care of patients in wards and clinics on a daily basis, and so have a sense of what physicians want from computers. I have been asked by this committee to address four issues: 1) the methods by which information systems should be verified and regulated, 2) what should be done to assure timely recertification of such systems, 3) who should be allowed to use these systems, and 4) what should be done to protect confidentiality of computer-stored medical records.

The sense of some of these questions suggests some people expect more from artificial intelligence than it is likely to deliver. There may also be misconceptions about the nature of medical practice, and the kinds of tools that physicians need and will accept.

First, it should be pointed out that artificial intelligence is not the only means by which computers can do intelligent things in medical practice. It is one of

many available methods which include: statistical decision theory, mathematical control theory and just plain old programming. Moreover, these latter approaches have been around much longer than artificial intelligence and have been used long enough in real clinical settings to gain insight into the kinds of problems they may cause.

The history of medical computing goes back to at least the early 60's. Progress has been steady but slow. In 1964, Homer Warner published a landmark report about a computer system that could diagnose congenital heart disease with a 90% accuracy. This program used Bayes statistical techniques. Dr. DeDombel from Leeds, England has used a similar approach in a computer program that diagnoses the cause of abdominal pain very successfully. His program has been used in many countries.

Plain old programming has also made important contributions. In the mid 70's Howard Bleich and co-workers from Beth-Israel hospital in Boston, developed a plain old program that acted as a proficient consultant about acid base disturbances. The physician could enter information about a patient. The computer, in return, would provide advice about both diagnoses and treatment. This program was made available in over thirty Veteran's Administration Hospitals.

In the mid 1970's investigators at Massachusetts General Hospital, the University of Utah and my own institution, Indiana University, implemented rule-based systems that would review a patient's computer -stored record and remind physicians about conditions needing attention. These too were based on plain old programming. In controlled trials, we were able to show that among eligible patients, physicians increased their use of preventive care such as influenza vaccine, mammography and cervical Pap testing two-to-four fold compared to control physicians who did not receive computer reminders. Our first study of this system was published in 1976.

In the late 70's a major drug company marketed a system for diagnosing pediatric diseases. Physicians could dial up to the remote computer, enter three or four findings to get back a list of possible causes, including the hard to remember congenital syndromes. In the mid 70's, computer diagnosis of electrocardiograms was developed and since has been successfully commercialized. Currently, around 10% of all the electrocardiograms in this country are read by computer. These systems use plain old programming to make their diagnoses.

In the late 1970's, studies of the use of computers to manage intravenous infusions such as fluids, blood and IV medicines were undertaken. Computer controlled infusion

machines are now quite successful. They can reach a target goal, such as a normal blood pressure, much faster and with less overshoot than conventional manual methods. These systems are based on mathematical and control theory, the same techniques computers use to land a 747.

There has been no mad rush by the medical community to install the above systems despite their demonstrated benefits. Physicians hardly used the services of the acid base consultants or the pediatric diagnostic program when they were made available and as a result, these two programs were removed from the "market". Some of the other systems mentioned above have spread to other sites, but the spread has been slow, certainly much slower than the growth in use of imaging techniques such as CAT scans and ultrasound. These observations should assuage any concern that physicians will rush out, buy new diagnostic computers and apply their advice willy-nilly.

Difficult logistic, practical, organizational, and theoretic problems hinder the adaptation of such systems. One such problem is that the interface between physicians and computers is still too slow. The development of faster methods by which physicians could communicate with computers is currently a subject of important research work both in artificial intelligence and other laboratories. Until improved methods are available the physician time

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cost of "talking" to computers is too high for long consulting dialogues. Consequently, decision support systems will be most successful when they can make their decisions on the basis of internally-stored data, for example from a computer-stored record. But, building computer-stored records is difficult because of lack of standards for communicating clinical data from one computer system to another, for example from a laboratory system to a medical record system.

In addition there is still a great deal to learn about how to assist physicians in making decisions and when they need help. Finally, there is a real dearth of empirical data on which to base detailed rules about how to take care of patients. Though medicine pats itself on the back for all that it has learned in the past 50 years, we have learned only a small fraction of what there is to know. And consequently, much of what experts say are simply guesses.

Artificial intelligence has made and will continue to make important contributions to the field of medical computing. But it is not a magic bullet and will not simply sweep away the above problems. Considerable research, such as that supported by the National Center, and National Library of Medicine, are required to develop the ideal consulting system. Moreover, artificial

intelligence will not be the only approach applied to decision support systems. Statistical techniques will also be important as computer-stored clinical data becomes available in greater amounts with the increasing automation of medical data.

Another possible misconception is the notion that physicians would turn to the computer and take its advice as they would from their consultant colleague. This is science fiction. Let me explain. First, a computer will not know as much about the patient as a physician. The physician gathers immense amounts of information about a patient by simply watching the patient's gait, the quickness of their verbal response, the light in their eyes, the tone of their voice, and so on. In fact, in an instant, the human observer watching a patient walk into their office knows the patient's approximate age and their sex. They also know that the patient is not unconscious, has no significant neurologic disturbance, has not swallowed a cyanide pill, and has not suffered a gunshot wound and so on. It would take a long session between physician and computer for the physician to inform the computer of all of these observations. And physicians simply are not going to spend large chunks of their day explaining the full status of their patients to computers.

In the time it would take to do so, the physician could complete the work of an entire patient visit.

Finally, even if the computer knew all that the primary physician knew about the patient, it may not know as much about the patient as the consultant would. One of the most valuable contributions a human consultant makes is the separate history and physical they perform. A consultant's discovery of an unnoted historical fact, or the small lump on the thyroid may contribute more to the diagnosis than their special knowledge about the diseases.

Finally, there are potential problems with the coupling of physician descriptions of patients to the computer's internal thresholds for making decisions. Physicians often disagree about how loud a heart murmur is, or how deep ankle edema is. Thus, an expert system is likely to differ when different physicians describe the same patient.

In sum, the idea that physicians would take a risk with a patient simply because the computer told them to, is naive. Cardiac arrest alarms often sound for patients who are sleeping quietly or eating lunch. But physicians never run in to cardioshock such patients. When a lab test comes back with an unusual abnormality, physicians don't rush to treat it. They assume it is wrong, and repeat it. By habit and training physicians trust their own observations

and views far more than those of others. Second and third year residents often disdain the advice of a senior staff member, we can hardly expect that such physicians will blindly take computer advice. The experience of commercial electrocardiogram diagnosis systems -- the only commercial success of computer diagnosis systems -- is instructive. Almost every commercial system offers cardiologist over-read of the computer-read EKG's. More important, the cardiologist over-read is requested in more than half of the electrocardiographic workload of some companies.

None of this is to say that computers won't provide useful and important help to clinical care. On the contrary, I think computers can radically improve the efficiency and reduce the error rate in medical care. Such systems will have the greatest potential when they can make decisions solely on the basis of information captured from instruments such as electrocardiograms, blood pressure readings and so on. And in these cases, when no human intervenes between the primary data and the decisions, standards may be needed. But for ordinary medical decision making, the computer outputs will only be an assist to the physicians decision process. There are likely to be a great variety of different kinds of assistance systems. Some will provide easy access to precisely the information

wanted from textbooks and journals. The success of these systems might be measured by the relevance and conciseness of the retrieved information. Others will help physicians who are searching for diagnostic or therapeutic ideas in the difficult patient who does not respond to the usual therapies. The quality of these systems might be judged by the comprehensiveness of the options they offer. Still other systems might remind about the dangers of a particular drug, in light of the patient's clinical history, or about a diagnostic possibility not currently under consideration. The absolute accuracy of these reminders may not be important as long as they offer good ideas often enough to be worth reading. Certainly, diagnostic assistance programs will not have to be 100% correct to be helpful. In fact, almost nothing is 100% in medicine. Physicians are accustomed to high rates of false positives and false negatives from test results. For example, when a mammogram suggests the presence of breast cancer, the true chance of breast cancer is less than one out of four or five. Yet, mammography is a very useful test because it detects cancer early enough to cure. Thus, we can afford to accept some false positives to find the patients with true positives.

Other systems may suggest very specific dosages, or

intervals of testing based on cost benefit calculations. On a simple scale, such calculations are now being done in many hospitals to decide the dosages of some intravenous antibiotics and asthma medications. Such systems do reduce drug toxicity and inadequate therapy. Finally, some decision support systems will contain no baseline medical knowledge. They would be intended to execute rules fed in by the local physician according to personal standards of care.

We doubt that decision support techniques will be in any way equivalent to human consultants. Consequently, we think it is premature to even discuss the development of formal standards for medical decision support systems. We understand too little about the physician's real decision processes, and even less about where they need help in this process. We can envision a great variety of such systems with wide variety of goals and purposes that would confound any uniform standard or regulation designed at this point in time. But we simply don't know exactly what the field will bring. Asking the field to define such standards now would be like asking Orville Wright how he would regulate the airline industry.

Moreover, considering existing legal and ethical forces, such as malpractice, and the traditional caution of

the medical profession, it is quite possible that external standards will never be needed. Certainly, there are strong parallels between the evidence provided by medical textbooks and monographs -- especially those that include flow charts and algorithms, and the guidance provided by a decision support system. Wrong or out-of-date textbook information has the same potential to misdirect the physician. Yet, we don't try to standardize or regulate the textbooks or other published advice. Market forces, physicians, and the publishing industry seem well able to distinguish the good from the bad in their reading. They should be able to do the same with medical decision systems.

Physicians tend to be overly suspicious and untrusting of computer systems and bothered by the time they consume. To impose standards on the field at this juncture could stifle an infant science would stifle the growth. The medical industry has been one of the slowest to use computers to reduce the cost and raise the quality of their "product". An overburden of rules and regulations would only add to the delay -- a delay we can hardly afford considering the medical care currently consumes 10% of the national product.

The question about how often databases should be

updated should be determined by those who use these systems. Remember, physicians have had from 9 to 15 years of post high school education in biology and medical sciences. They are well aware of the limitations of their information sources and they operate accordingly. Market forces have been adequate to determine the frequency of updating of classical medical textbooks. There is no reason to expect that similar forces will not operate as well on the computer support systems.

The question about what kind of individuals should be allowed to use these systems is a difficult one. On the one hand these systems are likely to be designed to specifically to assist physicians' decisions, and will assume that the user has the background and experience of a physician. It would be appropriate to prohibit commercial use of such systems by nonphysicians. On the other hand, it would be arrogant and presumptuous to legislate against the use of such systems by ordinary individuals for their own curiosity or interest. And we can be sure that some individuals will acquire and use such systems for these purposes. The consequences should be no worse than that of reading medical textbooks and journals intended exclusively for physicians or alternate health care books now on bookstore shelves.

The last question deals with the confidentiality of medical records. Clearly, it is important that medical information remain confidential. Technical means are available to provide almost any level of confidentiality required. In fact, a federal report details the range of security appropriate to various kinds of computer systems is available. The most extreme forms require large passwords, changed each day, narrow restriction of access by password, special shielding of rooms containing CRTs and computers, to prevent monitoring by microwave snoopers. They also require encryption of all stored information and elimination of any dial-up lines. But when trying to decide how much security is required, one must consider the costs. Obviously, there are dollar costs. Security keycard readers on every terminal could easily add 20-30% to the total cost of a hospital computer system. The costs of protective shielding to prevent microwave snooping could be prohibitive. There are other costs. The most difficult problems that physicians face on acutely ill patients is obtaining past information about that patient. I remember too well the hours it could take to obtain a hospital chart when I was an intern at Boston City Hospital. Today, a large chunk of every physicians day is spent finding, organizing and assimilating information about individual

patients. We need faster and easier access to our patient's medical information. Yet the more security protection we place on a medical system the more difficult the information will be to obtain. And even small barriers can make use of such systems by physicians difficult or impossible. A physician may practice in three or four different hospitals and have only an occasional patient admitted to any one of them. Thus, he may often forget his access code. How will he obtain his patient's records? If security allows him to access only his own patients, how will he review his partner's cases when cross covering? If a patient suffers a cardiac arrest how will the nearest physician be able to help? Finally, if security is so tight that it interferes with the routine operation of a hospital, people subvert it. It is not uncommon to see general passwords written on the side of CRTs in institutions where the password control is very tight.

Clearly, some level of security is required. A practical minimum might be to tightly limit access to programs that can search across patient records and display patient identifying information. And apply tight password control over terminals that are not in patient care areas. Physical location will tend to prevent access by outsiders in patient care areas, just as it does for the manual

chart. We don't believe it is practical to limit the medical or nursing staff access to only their patients because of the problem of cross coverage, rotations, and emergencies.

Institutions should have some way of limiting access to medical data about VIPs or other individuals who may be under a special threat of snooping. Similarly, the capability of restricting medical staff access to certain kinds of data, e.g., venereal disease tests, might also be desirable.

It would be much easier to determine the level of security required if measures of the real threat to privacy were available. How often do unauthorized personnel try to access medical records in the manual systems? Does anyone know? Hospital record rooms are rarely guarded. Anyone with a white coat can wander in and take a chart out. Billing records containing diagnoses and procedures, and laboratory results are transmitted between the hospitals and Blue Cross insurance companies and between laboratories and practices all over the country without any special encoding. Current operational procedures, thus suggest that the threats to medical privacy are minimal. But we need better estimates about the kinds of privacy threats that exist and their relative risk.

Curriculum Vitae

Clement Joseph McDonald, M.D.

Born Chicago, Illinois, December 16, 1940.

Married to Barbara McDonald, three children ages 7-11.

Degrees

University of Notre Dame	B.S., 1961. Completed coursework in three years.
University of Illinois	M.D. 1965. Academic rank, 1st in class.
Northwestern University	M.S., 1968. Focus on computers and mathematics. Thesis - Computer Diagnosis of the Acute Abdomen by Computer Pattern Recognition Methods

Postgraduate Medical Training

Internship, 1965
Boston City Hospital, Harvard Medical Service

National Institute of Health Fellow, 1968-1970
Managed development of the first computing clinical laboratory system at the clinical center in Bethesda, Maryland.

Internal Medicine Resident, 1970-1972
Cook County Hospital and University of Wisconsin.

Academic and Professional Positions

1972 - present

Professor or Medicine, Indiana University School of Medicine, Department of Medicine.

Staff physician, Wishard Memorial Hospital, Indiana University Hospital and Regenstrief Health Clinic.

Director of Computer Science Research, Regenstrief Institute for Health Care, Indianapolis, Indiana.

Research Activities

Developed and studied computer-stored medical record and rule-based physician reminder system. Developed database management systems, clinical laboratory, pharmacy and appointment scheduling systems.

Professional Activities

Secretary of Executive Board for Symposium on Computer Applications in Medical Care.

Executive Board, College of Medical Informatics

Managing Editor, M.D. Computing, a Springer-Verlag international journal.

Reviewer for the New England Journal of Medicine, Annals of Internal Medicine, Journal of the American Medical Association and others.

Selected Publications

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McDonald J: Computer reminders, the quality of care and the nonperfectability of man. N Engl J Med 1976; 295: 1351-1355.

McDonald CJ: Computer diagnosis of acute abdomen. Master's thesis, April 1968.

Mr. VOLKMER. Thank you very much, Dr. McDonald.

Mr. Belair.

Mr. BELAIR. Thank you, Mr. Chairman.

I always tell clients that if they're the last witness of the day, that they ought to make it very, very brief. Of course, they usually don't pay any attention to me, but I will try to take my own advice and make this brief.

Let me commend you, Mr. Chairman, and the members of your subcommittee, for taking an interest in health record privacy. I'm sure it's not for a lack of other things to do, and this is an issue—it's a difficult issue, it's an insidious issue, it's one that does not have easy answers, and it requires a lot of work, and, judging by your questions here at the earlier panel, you're obviously prepared to do a lot of work and have done a lot of work, and so I certainly commend you for your interest.

Let me briefly summarize the state of privacy law today as it relates to health records, and, in a sentence, the state of that privacy law is very poor; it's very unprotective of patient interests in confidentiality and privacy and provider interest as well.

For example, the law ought to provide for a sure and easy and ready way for patients to have access to their health records, and although we've made a lot of progress in that area, the law is still, by no means, a predictor or an insistor on patient access at all times.

We ought to have a law that has very sharp limits on the dissemination of health record information to third parties, obviously the key to much of privacy and confidentiality law, and in fact the law today seldom does.

We need very desperately to have effective controls on the redisclosure of health record information by third parties. Today, as we all know, in this room there are a myriad of third parties who do not provide health care and who, nevertheless, must have access to health records for payment purposes, for research purposes, for employment purposes—and employers are increasingly involved in this in the health care process. Nevertheless, all too often when these kinds of parties get hold of health record information, the controls on their redisclosure and reuse of this information are inadequate.

Automation—there's been a lot of talk, obviously, today about automation. The bottom line, I think, from a privacy standpoint is that automation of health records simply makes it easier to collect the information in the first place, easier to retain it, cheaper to retain the information, and easier and cheaper to say yes to requests for the disclosure of the information.

It doesn't mean by any means—and this is why it's such a difficult issue—that we ought to be opposed to the automation of health records. Indeed, as a couple of the folks here this morning have pointed out, there are some real benefits from a privacy standpoint for automation. It is often easier to protect the information in an automated system, easier to introduce data quality protocols that update information, that have logs that keep track of dissemination, and so forth, but, nonethless, there is a threat.

For example, when we're talking about the use of computers for diagnosis and diagnostic systems, what that runs the risk of doing

is increasing the amount of information about specific individuals, personally identified individuals, in automated systems. It doesn't have to, but we certainly have that risk.

Another especially troubling area of the law is that the Federal Government, which has such a key role today in health care—as a provider of health care, as a sponsor of health care, as a payer for a great deal of the Nation's health care, as a researcher in public health—the Federal Government is intimately involved in virtually every aspect of health care today.

We ought to be a model, here at the Federal level, for how health record information is collected, and used, and disseminated, and although the Congress has made efforts in this regard—and I suppose the most important effort is the Privacy Act of 1974—the fact remains that we've got a long way to go.

The Privacy Act was a bad law 12 years ago. It hasn't gotten any better; it's gotten worse. It simply fails to introduce adequate protections on the collection, and the use, and the redisclosure of health record information, and my statement goes into some of these issues in a little bit more detail.

Let me close by addressing, I think, something that we've always got to address when we're talking about reforming law, and I know that Members of the Congress feel this acutely, and that is, "So what? Why do we care about improving, enhancing the protections for patient privacy?"

We care, in part, I think, or ought to, because the public cares. Every public opinion poll that's been taken on the issue of privacy shows that the public cares most about the privacy of their medical records, more than financial records, more than educational records, employment records—any other kind of record.

Second, there are real adverse effects that flow from the improper disclosure or use of health record information, tangible effects: People lose jobs, they lose promotions, they lose opportunities for insurance, they lose opportunities for credit; there are adverse relational effects: relations with family members, with spouses, or friends are interrupted and, in some cases, destroyed.

Therapeutic effects. The doctor-patient relationship is built, in some measure, on an element of trust that a patient can be candid and forthcoming with his physician and that that information won't go any further. That underlies the old pledge of confidentiality and the Hippocratic Oath.[46a] I think it explains why virtually every provider organization—AMA [American Medical Association]—the American Psychiatric Association, the AHA [the American Hospital Association] all of the major health associations have either published model confidentiality laws or they've adopted positions which are supportive and comprehensive on the question of privacy.

Obviously, too, there are devastating personal effects—stigma and embarrassment, emotional distress, trauma. What we don't have, as Dr. McDonald so rightly pointed out, is any empirical in-

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[46a] The Hippocratic Oath states, ". . . And whatsoever I shall see or hear in the course of my profession . . . , if it be what should not be published abroad, I will never divulge, holding such things to be holy secrets." (John Bartlett, "Familiar Quotations," 15th Ed. (Boston: Little, Brown and Co., 1980), p. 79.)

formation. We don't know what the cost is; we don't know what the incidence is; we don't know how pervasive it is. We've got lots of anecdotal information, and I put some of it in my prepared statement.

I used to be the general counsel of something called the National Commission on the Confidentiality of Health Records, and that's a now defunct organization, but we used to get over 100 complaints a month from patients about the invasion of their privacy, and I just pulled the first 5 off the top, and they are mentioned in my statement.

A Sulphur, OK, woman who lost her marriage when it was improperly disclosed that she'd been tested for VD; a Kansas City woman who lost her job after her employer was told that she suffered from severe depression; a Russellville, AL, woman who suffered a severe emotional distress after pictures of her breast implant surgery were improperly disseminated and circulated; an Evergreen Park, IL, woman who was denied entrance to the sisterhood after the mother superior was told by a Catholic hospital that this woman had been under psychiatric care; a Cushing, OK, woman who suffered severe emotional distress—and I had some personal communication with this woman at the time. She was one of the grand dames of Cushing, OK, 90 years old, and it was disclosed improperly that she was being treated for syphilis. There is an awful lot of damage that's out there. We cannot quantify it yet, and we need to.

By way of conclusion, let me just reference an article that appeared in the New England Journal of Medicine that's mentioned in my statement. Dr. Mark Siegler kept track of the number of individuals affiliated with a hospital who get to look at a typical patient's health record while the patient is in the hospital. He counted 76 individuals, from the doctors on down to the candy-stripers, and his conclusion, based on that and some other factors that he took into account, was that privacy as it relates to health information is dead, it's a myth.

I think that's a misdiagnosis, at least a premature diagnosis. It isn't dead, but it certainly is ill, and we need to take a good, hard look at the law. That can be done in a way that's progressive, in a way that does not stop the kinds of initiatives that we heard about here today. It takes thought, it takes cooperation, we have to be clever about it, but it can be done, and the NCCUSL has now adopted, and the ABA has unanimously endorsed, a model State law that addresses many of these issues.

The NCCUSL, as you know, is good; they've got a good track record at getting their statutes adopted at the State level. So I'm optimistic that it will move.

I think that's an initiative that the Congress needs to follow, and then I think at the Federal level the Congress needs to take a look at the Privacy Act, take a look at the role that the Federal Government plays in health care, take a look at automation and adopt legislation ultimately that addresses health care and the handling of health records at the Federal level.

Thank you.

[The prepared statement of Mr. Belair follows:]

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TESTIMONY OF ROBERT R. BELAIR
BEFORE THE HOUSE SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT OF THE
COMMITTEE ON SCIENCE AND TECHNOLOGY

April 21, 1986

Mr. Chairman, I am Robert R. Belair, a partner in the law firm of Kirkpatrick & Lockhart, in Washington, D. C. I am pleased to have this opportunity to address the Subcommittee concerning the status of privacy law as it relates to health records and, in particular, computerized health records. Before beginning, I want to commend the Subcommittee and its Chairman for their interest in this vital, but often neglected, issue.

INTRODUCTION

Before proceeding with my statement, I would like to describe briefly my background. I have devoted a good deal of my professional career to problems related to health record privacy and other privacy issues. I have served as a staff member for the National Academy of Sciences' Project on Computer Data Banks, which produced a landmark report entitled Data Banks in a Free Society. I have also served as the Deputy General Counsel of the Domestic Council Committee on the Right of Privacy in President Ford's Administration.

Since leaving government, I have served as General Counsel of the now defunct National Commission on the Confidentiality of Health Records, a federation of 21 health professional organizations dedicated to enhancing the confidentiality of health records. More recently, I have served as a reporter for the National Conference of Commissioners on Uniform State Laws' ("NCCUSL") Drafting Committee on Health Record Privacy. In 1985, the NCCUSL adopted the model Health Records Act and since that time the Act has been unanimously endorsed by the American Bar Association. I have also written and spoken extensively on the subject of health record privacy.

In my remarks this morning I would like to talk first about the importance of health record privacy. Following that I will summarize confidentiality and privacy law as it relates to collection, maintenance dissemination of health records and patient access to these records. Finally, I want to focus on a few particular problems, including the automation of health records, that I think deserve Congressional scrutiny and action.

HEALTH RECORD PRIVACY IS THREATENED

Every public opinion poll that has addressed the issue of health record privacy finds that the American public is vitally interested in protecting the privacy of health records. Despite this interest, the extent to which Americans enjoy health record privacy has declined dramatically. Not long ago, Dr. Mark Siegler published an article in the prestigious New England Journal of Medicine (December 9, 1982) entitled, "Confidentiality in Medicine -- A Decrepit Concept".

Dr. Siegler kept track of the number and type of hospital employees who reviewed an "average" patient's record. The result was startling. Dr. Siegler found that the average patient's record was reviewed by 6 doctors, 12 hospital officers, 20 nurses on three shifts, 6 therapists, 3 nutritionists, 2 clinical pharmacists, 15 students, 4 unit secretaries, 4 hospital financial officers, and 4 hospital reviewers. Siegler concluded, "Let's not perpetrate the myth of medical confidentiality -- it no longer exists."

Unfortunately, we do not have empirically valid data regarding the extent to which hospital and other health care records are reviewed or disseminated. What we do have, however, is an impressive body of anecdotal reports. For example, a Sulphur, Oklahoma woman lost her marriage when it was improperly disclosed that she had been tested for VD; a Kansas City woman quit her job after her employer was told that the woman was being treated for severe depression. A Russellville, Alabama woman suffered severe emotional distress after pictures of her breast implant surgery were improperly circulated among hospital employees. An Evergreen Park, Illinois woman was denied entrance to the Catholic sisterhood after a Catholic hospital disclosed to the Mother Superior that the woman had a psychiatric record. A Cushing, Oklahoma woman suffered severe emotional distress after it was disclosed within the community that she was being treated for syphilis -- she was 90 years old. (Compiled from the records of the National Commission on the Confidentiality of Health Information).

ADVERSE EFFECTS OF PRIVACY INVASION

Stories such as these are endless. The reason, of course, is that the improper disclosure of health record information can, and often does, have significant adverse effects on patients. Such disclosure adversely affects opportunities for jobs, promotions,

the granting of credit, and insurance. Moreover, disclosures of health record information can disrupt relationships with family and friends. Some years ago, for example, I represented a newspaper editor whose marriage suffered after it was disclosed that, prior to their marriage, he had been arrested for sexual assault and had been treated for psychiatric and emotional problems at that time.

Furthermore, disclosure of health record information destroys the trust that health care providers are quick to acknowledge provides a necessary basis for a provider-patient relationship. Moreover, psychiatrists and other professionals have documented that the disclosure of health record information often results in feelings of shame, humiliation, betrayal, loss of status and face, and loss of control. In short, the unexpected, inappropriate disclosure of health record information is demeaning -- it's an assault.

SOCIETAL DEVELOPMENTS WHICH
HEIGHTEN THE THREAT TO PRIVACY

Over the last several decades a number of fundamental developments have increased the threat to the confidentiality and privacy of health care information. These developments include the emergence and growth of third-party payment plans; the use of health care information for non-health care purposes; the growing involvement of government agencies in virtually all aspects of health care; the declining role of physicians in providing health care (in the early part of this century, 85 percent of all health care providers were physicians; today physicians make up only 5 percent of the total. Dilemma -- A Report of the National Commission on the Confidentiality of

Health Records, p. 2 (1977)); the emergence of corporate, multi-state health care providers; and the exponential increase in the use of computers and automated information systems for managing health care record information. Privacy Protection Study Commission, Personal Privacy in an Information Society, at 283 (1977) (hereafter "Privacy Commission Report").

SUMMARY OF PRIVACY LAW

Notwithstanding the growing threat to health record privacy and the public's interest in preserving such privacy, the fact is that privacy laws have failed to keep pace. Only one-fifth of the states, for example, have adopted comprehensive privacy acts -- based more or less on the 1974 Federal Privacy Act -- which provide some assurance that health records held by state government agencies (but not the private sector) will be disclosed to third parties only after first obtaining the patient's consent. See, for example, Arkansas Statute Annotated § 16-802 et seq.; Connecticut General Statute Annotated § 4-190 et seq.; Indiana Code Annotated § 4-1-6-1; Mass. General Laws, Ch. 30, § 63, Ch. 66A; Minnesota Statute Annotated § 15.162 et seq.; Ohio Revised Code Annotated § 1347.01 et seq.; Utah Code Annotated § 63-50-1 et seq.; and Virginia Code § 2.1-377 et seq.

Only two types of health record legislation are common in virtually every state. First, statutes in every state require health care providers to report many types of patient information to state agencies. Typically, these statutes require providers to report health data concerning violent injuries (gunshot and knife wounds are most common); contagious or infectious diseases; tuberculosis; veneral disease; occupational illnesses and injuries; certain congenital defects; and injuries from child abuse.

Second, almost every state recognizes some type of provider-patient privilege. The privilege generally permits the patient to prohibit his provider from disclosing health record information in at least some types of judicial proceedings. (South Carolina, Texas and Vermont do not have doctor-patient privilege laws.) However, the privilege belongs to the patient and thus can be waived by the patient. Moreover, many statutes include express exceptions which allow providers to provide information to a court in connection with court-ordered examinations; where child abuse is at issue; where involuntary hospitalization is at issue; where the patient relies upon his medical condition as a defense; and in cases of criminal prosecution.

Only a few states (Rhode Island, California and Montana, most notably) have adopted comprehensive health record privacy statutes which regulate the collection, maintenance and disclosure of health records by private sector providers. In jurisdictions without comprehensive statutory schemes, private sector health care providers enjoy broad discretion to collect, manage and maintain patient records.

However, even in the absence of statutory standards, health care providers do not enjoy unfettered discretion when it comes to the disclosure of health records. In most jurisdictions the courts have held that providers must have the patient's consent in order to disclose records. Disclosures without such consent can result in tort liability -- on the theory that disclosure represents the publication of private facts -- or can result in liability in contract -- on the theory that there is an implied contract of confidentiality between providers and patients. See, Decisions: Judicial Decisions in Health Records Confidentiality (1979). However, under these common law theories the courts recognize numerous exceptions which permit providers to release health record information without patient consent to third-party payors, law enforcement agencies, public health agencies, researchers and other third parties who provide services to providers or to society at large.

CONTENT AND MAINTENANCE OF RECORDS

When the current law is reviewed in regard to specific record-keeping activities, the inadequacy of current law becomes even more apparent. For example, although most health care providers have an obligation to maintain health records, the content of the records is left to industry standards. Interestingly, many hospitals take very seriously their obligation to maintain health records. For example, it is reported that St. Bartholomew's Hospital, in London, still has patient records dating from the year 1137.

However, the absence of criteria for the content of health records means that the information in such records is not held to a relevancy standard. Virtually any type of data a health care provider wishes to collect can be placed in the health record. The Joint Commission on the Accreditation of Hospitals does impose certain record content standards on hospitals. However, these standards are not directed at the protection of privacy.

Beyond a general requirement found in most state laws that at least institutional health care providers, such as hospitals, are required to maintain a patient's record for a set period of time, there is little in the way of regulation of the maintenance of these records. Occasionally, on a common law basis, courts have held that hospitals must expunge or correct health records. Wolfe v. Beal, 384 A.2d 1187 (Pa. 1978). Normally, however, the courts reject such efforts.

The courts have also rejected the argument that patients have an interest in whether or not a record is computerized. In Volkman v. Miller, 383 N.Y.S.2d 95 (1976), a New York State court held that there was no violation of a patient's privacy interest for the provider to computerize out-patient psychiatric records.

PATIENT ACCESS

Perhaps the area that where lawmakers have made the most progress relates to patient access and review of records. Today, about 30 states have adopted some type of patient access statute. In some states the statutory requirement affects only hospitals, and in still other states the access requirement affects only governmental health care providers. Moreover, the statutes which require providers to allow patients to review, and in some cases, correct their health records usually make exceptions for mental health information, or for those instances in which a provider believes that patient access would be injurious to the patient's health. Auerbach & Bogue, Medical Records: Getting Yours, Public Citizen Health Research Group (1980).

A few courts have held that even in the absence of a statute patients have a common law right of access (notwithstanding that the courts have also held that the health care record is the property of the hospital and belongs to the hospital or other provider). Cannel v. Medical and Surgical Clinic, 315 N.E.2d 278 (Ill. 1974); Wallace v. University Hospital of Cleveland, 170 N.E.2d 261 (Ohio 1960); Hutchins v. Texas Rehabilitation Commission, 544 S.W.2d 802 (Tex. 1976).

Even as regards patient access, the state of the law is by no means entirely rosy. Perhaps the key problem is compliance. While no definitive studies have been done, there is much anecdotal evidence to suggest that providers frustrate patient access laws by failing to provide the record on a timely basis, or by providing only an oral or written summary of the record. Many providers, of course, worry that patient access laws only encourage malpractice suits. For example, one study conducted in Massachusetts in 1983 found that hospitals in that state routinely failed to comply with the state's patient access law. One hospital official, in explaining compliance failures, stated, "Good medicine is good law." Many respondents to the Massachusetts survey cited a notorious Massachusetts incident in which a 33-year old lawyer committed suicide after reviewing his psychiatric record.

DISCLOSURE TO THIRD PARTIES

Disclosure to third parties is, of course, the principal privacy threat. One of the most frustrating and ironic aspects of the health record privacy problem is that the most serious and invasive disclosures to third parties are done entirely with patient consent. Studies indicate, for example that patients routinely sign virtually any type of consent form put in front of them, no matter how overbroad or vague. Rosen, Why Clients Relinquish Their Rights to Privacy Under Sign-Away Pressures, unpublished monograph, 1983; Informed Consent -- Why Are Its Goals Imperfectly Realized?, N. Engl. J. Med. 1980 at 896. Both statute law and case law has generally blessed the use of even the most overbroad or vague consent forms.

The Privacy Protection Study Commission's recommendations, the Model NCCUSL Bill, and model health care legislation proposed by virtually every major health professional group, including the American Medical Association, the American Hospital Association, the American Nurses Association, the American Psychiatric Association, and the American Medical Record Association, have recognized that overbroad patient consent forms are perhaps the most insidious threat to patient privacy and all of these organizations have urged legislators to restrict the use of such consent forms. These model proposals would require that patient consent specifically identify the records to be disclosed; the purpose of the disclosure; the identity of the party disclosing the record; the identity of the recipient; and restrict the applicability of the consent to a limited time period, usually one to two years.

As noted earlier, existing law also recognizes the right of providers to disclose health record information even without consent to a number of types of recipients. These recipients customarily include other health care providers or parties assisting health care providers; third party payors (although

usually third party payors are careful to ensure that they have obtained a blanket patient consent); law enforcement agencies; public health and other authorities who obtain information under compulsory reporting laws; researchers; employers; family members; parties with a need to know in emergency situations; and parties in danger and as to whom providers have a duty to warn. In general, the courts have held that disclosures to these types of recipients do not violate a patient's common law right of privacy in health records because there is a qualified privilege to disclose health care information for purposes of providing health care, obtaining payment, protecting the public health, and assisting law enforcement agencies, among other purposes. Hague v. Williams, 181 A.2d 345 (1962); Pyramid Life Insurance Company v. Masonic Hospital Association, 191 F. Supp. 51 (Okla. 1961).

AUTOMATION OF HEALTH RECORDS

The automation of health records and record systems is an issue of special importance. Computerization of health records does not change the rules, just the risk. Automation, in the words of the Privacy Protection Study Commission, makes it easier to say "yes" to requests for disclosure. Automation also makes it easier, and cheaper, to maintain a great deal of health record data that may not be needed. Automation also encourages the centralization or linking of information about a single patient so that a more comprehensive and detailed profile is available. Finally, automated systems, as is well known, are vulnerable to unauthorized penetration. For example, a couple of years ago a 21-year old used a $1,200 Apple II and the Telenet Communications System to gain access to Sloan Kettering's patient radiation records.

Of course, the effect of automating health record systems is by no means entirely negative. For one thing, automation promotes the standardization of data elements and language, thereby minimizing chances for mistakes or misunderstanding. Furthermore, automated systems are usually more auditable than manual systems because the record-keeping events are identifiable and recallable. Moreover, the quality of the data in automated record systems is often improved because the updating and correcting of data is easier. Finally, and perhaps most importantly, automating a system requires everyone involved in the system to be more thoughtful about the process and often results in real benefits from a privacy standpoint.

Nevertheless, the privacy threat posed by automation probably outweighs the privacy benefits from automation. In the last Congress, Representative Ron Wyden (D-Ore.), introduced legislation that would have restricted access to federal health records in automated systems. While this approach may not be perfect, the Congress should act to require federal health care providers to take steps to avoid the adverse privacy impact of automated health record systems. This would mean mandating the upgrading of computer security, limitations on the length of time that health care information can be maintained; limitations on the kind of health care data that can be maintained in an automated environment; and mandated data quality standards.

GOVERNMENT ACQUISITION OF HEALTH RECORD DATA

Another issue that should be addressed by the Congress relates to federal government's ravenous appetite for health record data. The federal government's role as a near-ubiquitous third-party payor; its role as a law enforcement agency; its role in public health; and its role as a researcher makes

the government a seemingly insatiable consumer of health record data. Compulsory reporting statutes, in particular, threaten to deputize every health care provider in the country and make that provider part of the law enforcement system. The long-term effect of federal demands for health care data threaten to have an adverse impact upon the quality of health care and the quality of our citizens' lives.

The Congress should look for ways to sharply limit the government's acquisition of health record information. Whenever possible, the government should make special efforts to obtain health care information in non-indentifiable formats or promptly transfer records into such formats. Whenever possible, the government should ensure that it uses health record information only for the purpose for which the record was first obtained. Whenever possible, the government should seal or destroy health record information. Finally, the Congress should insist that the federal government take the lead in using patient consent forms that are protective of personal privacy.

FEDERAL GOVERNMENT SHOULD BE A MODEL

In 1979, the Congress gave serious consideration to adopting federal legislation to protect the privacy of health records. S.503 and S.865, and see Hearings Before the Committee on Governmental Affairs of the United States Senate, 96th Congress, 1st Session. Unfortunately, objections from the law enforcement community that the legislation went too far in protecting privacy, and objections from the mental health community that the legislation failed to go far enough, doomed the legislation. Since that time the Congress has not seriously revisited this issue.

However, despite the Congress' inattention, the problem has not gone away. Indeed, the problem has become acute. Thanks to the efforts of the NCCUSL and the American Bar Association, the states now have before them a model bill that effectively addresses many of these problems. Hopefully, the state legislatures will act with dispatch to adopt this legislation. This effort should be monitored in the Congress. In the meantime, the Congress should act to make the federal government, which in and of itself is a major health care provider, a model for health record privacy.

Thank you for this opportunity to present my views on this vital subject.

Mr. VOLKMER. Thank you very much, Mr. Belair.

Let me ask a question, right at the beginning, of you, pertaining to those records. Do you see more problems in the future with the computerization of medical records and dissemination—unauthorized dissemination because of the computerization?

Mr. BELAIR. No question. It just makes it easier. It's so much cheaper to get that data, keep it a long time; you can disseminate it almost with the push of a button. It just introduces lots of incentives to move this data around, to centralize it, and if we're not vigilant, the technology will outflank the protections in current law.

Mr. VOLKMER. What about collection and storage of patient data that's not immediately needed for treatment? What can we do with it? Purge it?

Mr. BELAIR. You see, it's such a hard question. You know, the physicians will tell you—and I don't think that they're wrong—that if you start putting limits on the amount of data that physicians can keep or the kind of data that they can collect or keep, what you will do is adversely impact on health care.

There aren't any easy answers here, Mr. Chairman, unfortunately. I think that what we need to do is try to find ways to put this information in a nonpersonally identifiable format or at least to limit the number of people and the kind of people who have access to this data in a personally identifiable form—in other words, make the records anonymous to the extent that we can.

That's one answer, and the other answer, I think, goes to dissemination. The collection has to be—I think you'd have to be awfully intrepid to go in and begin telling physicians what they can and can't collect.

Mr. PACKARD. Mr. Chairman, would you yield on that point?

Mr. VOLKMER. Yes, I yield.

Mr. PACKARD. Why couldn't there be a key—a computer key to each patient's records that would only permit authorized personnel that have that key access to that information? It would appear to me that technology could answer that better than perhaps some other system.

Mr. BELAIR. I think they could, Mr. Packard. That's the kind of promise that the technology has. It's not all onesided by any means. What you hear is what we've heard this morning—and maybe Dr. McDonald wants to speak to it—and that is, "Gee, that makes it hard for physicians."

Physician convenience ought not to be a barrier to the imposition of adequate safeguards; it simply can't be, and if we end up inconveniencing physicians a little bit, they're just going to have to find ways, I think, to reorient their schedule and their activities to account for that. I simply don't think that that's a compelling concern.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. VOLKMER. I see.

Would you wish to comment on the description made earlier in the first panel by Dr. Gardner of the, quote, HELP system and the security that they've placed on it for physicians so that they have to be coded even to enter into it?

Mr. BELAIR. Are you talking to me, sir?

Mr. VOLKMER. Yes.

Mr. BELAIR. I'm sorry.

Gee, you know, I don't know enough about that system to really—it wouldn't be fair for me to pronounce whether I think it's a good or bad system. It certainly sounds like they're aware of the security issues and they're trying to address them.

Mr. VOLKMER. OK.

Professor Brannigan, you discuss in your oral testimony and your written testimony the applications of strict liability as against the use of negligence. Would you think that this is sufficient—and as I read it, it appears to be sufficient—to do the regulation—that would be sufficient as far as regulation is concerned?

Professor BRANNIGAN. In an article, which I'll be happy to send to you, I argue that point in the Journal of Consumer Policy in 1983—was that strict liability for injuries acts as an adequate self-regulatory effort in this particular area because the institutions are really responsible and they know it, and therefore there's no way they can dodge it, and my research conclusion is that that is correct, that strict liability is adequate to guarantee a very high level, and trying to guarantee perfection would stifle the technology.

[The article follows:]

Current Developments in Consumer Law

Vincent M. Brannigan

Compensation or Regulation: The Problem of Medical Computer Software

ABSTRACT. Medical computer software represents an excellent example of the difficulty of applying the law to developing technology. A society must decide which of the goals of efficiency, equity, or subsidy are paramount in the development of the technology.

The two legal tools available to achieve the goals are compensation (the paying of damages) and regulation (the direct control of the technology).

These tools are not well suited to the control of medical software, since the ephemeral decentralized technology is normally not able to be identified with sufficient exactness to permit regulation nor is it produced by any single individual or firm which would allow normal methods of compensation.

Thus the limitations of the legal tools make achievement of the social goals extremely difficult. This difficulty may force the society to choose a different combination of fi-ciency, equity, or subsidy which better reflects the ability of the tools to control the technology without stifling the technology.

Computer software is an excellent example of the problem of social control of technology through law. Compensation and regulation are the primary legal tools for coping with software defects. This paper offers some of the theoretical advantages and disadvantages of these two control mechanisms, along with some criteria used to assign a technological product to one area or the other, and investigates software problems which make these issues relatively difficult to decide (see Brannigan & Dayhoff, 1981).

This paper will address the particular problem of *medical* software. The use of computers in medicine has revolutionized certain aspects of medical care and has the potential to change it in fundamental ways. Virtually all new technological developments go through a sequence of invention, development, and stability. Often society becomes involved because of the need to cope with the inevitable problems of technological development.

Medical computer systems involve a wide range of new technologies. There are computer systems which directly control the machine that interacts with the patient; software on which the physician relies without independent checking; and computer systems used by the physician as a resource equivalent to a medical textbook. It is a challenge to the legal system to develop effective social structures for coping with these types of technologies.

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The Code of Hammurabi was one of the earliest regulatory approaches to technology. Crudely put, under that code, if a building collapsed, killing the owner, the architect was put to death. This clearly defined the responsibility of the private sector and avoided entirely the need for government regulation.

Since we no longer put professionals to death for mistakes, we use the two controls of compensation or regulation. In the modern environment, compensation tends to be in the form of malpractice or product liability; the injured person being compensated with money.

GOALS OF TECHNOLOGICAL CONTROL

In the area of technological control, there are three traditional, possible goals of the legal system. The first, an efficient level of safety, is described by most experts in this field as a minimization of the total cost of injuries and injury-reduction activities. All things being equal, as one regulates past that point, the cost of injury-reduction activities increases, so that both overregulation and underregulation are socially inefficient.

The second goal of the legal system is to achieve an equitable distribution of the cost of those injuries and injury-reduction activities. Economists who hypothesize an "efficient" level of injuries or safety do not normally address the question of equitable distribution, i.e., who should bear the cost of these injuries. Nevertheless, if computer programs are going to be the source of a certain number of injuries, then the question of who assumes the burden of that cost should be raised as separate and independent from the issue of an efficient level of safety.

Thirdly, the promotion of the use of a particular technology is characterized by the reality that our society often engages in subsidizing some developing technologies in order to encourage their use. Two classic examples are (a) air transport, which is subsidized on the international level by the Warsaw Convention limiting liability of air carriers for injuries caused to their customers; and (b) the Price-Anderson Act for nuclear power plants, which limits the liability of power plant owners and manufacturers in order to further development of nuclear power capabilities. These are generally considered subsidies regardless of whether the government agrees to pay the cost of mishaps or accidents, or, as is more common, restricts redress and recovery by consumers.

These three goals, efficiency, equity, and subsidy, are socially determined – usually politically determined – but they are not

technical questions. The challenge is, having decided on the goals, how do we achieve them through the legal system? Liability and regulation are two alternative means of achieving this social control.

REGULATION

The theoretical advantage of regulation is that society directly attains the level of safety it desires. What it does not have is direct control of the cost of the safety producing activity. It is one thing to stipulate the production of a safe product; it is quite another to guarantee a safe product at a socially efficient price. It is quite possible to regulate certain kinds of activities out of existence, because there is no way to achieve compliance at a price the society will pay. Thus, one of the disadvantages of regulation is that the cost of injury-reduction activities may bear no relationship at all to the benefits. Unfortunately, there is no automatic, self-limiting control over regulation to balance this equation. In a free-market economy devoted to promoting the widest variety of products, a common view is that the institutionalization of regulation has an anticompetitive effect, suffering as it does from problems of centralization, industry capture, and institutional bias. These problems are aggravated when the subject of the regulation is not easily regulated. This increases inefficiency and transaction costs.

Types of Regulatory Systems

Regulatory systems fall into two groups – permit and inspection systems. Permit systems, which require obtaining permission from the government to sell a product, have some inherent characteristics: (a) permits tend to centralize the examination process, enabling easy application of a standard; (b) a permit structure can offer considerable advantages to those manufacturers who are first to apply, and priority sometimes overwhelms technological superiority; (c) there is a tendency to use permits to centralize the producers; (d) it automatically creates a list of those who are affected by the particular statute; (e) failure to have the required permit is itself a crime or offense; (f) normally, the person who wishes to engage in an activity cannot engage in it until the permit is issued – therefore, normally, delay runs in favor of the government or in favor of not allowing the activity; (g) summary enforcement is relatively easy since permits can often be lifted or revoked on essentially a merely probable cause showing, although this question is not entirely free from doubt; and (h) if the government does not assign enough

qualified persons to review and grant the permits, there are two possibilities. Either permits will be granted which are not determinative of compliance – that is, in order to avoid the backlog of paperwork, permits are simply stamped and issued without establishing compliance – or there is simply an extremely long delay in the granting of the permits, which can lead to political and economic problems.

Regulatory control can also be exercised according to an inspection model. Here, inspectors search out systems to determine whether or not they comply with the approved set of standards. The advantages of this strategy are more or less the opposite of those of permit regulation. The characteristics of the inspection model are: (a) it does not automatically require particularly well-trained people. The effect of inadequate searches is normally to simply not generate any compliance activity. The nature of governmental agencies is that what they don't know normally does not show up in their records. Completely untrained persons can be assigned in the inspection model to go out and do various inspections, for example, and if they don't see a defect, there is no follow-up; (b) delay runs in favor of the private party; and (c) inadequate inspections are rarely discovered until a disaster occurs. Since the disasters are relatively rare events, the agency can go on for a long period of time thinking it has an adequate inspection program without any contrary evidence in the form of a disaster. Rather than benefiting a few producers, inspection serves to decentralize decision-making.

Regulating Software

The nature of software is such that it is particularly difficult to regulate. First of all, software is ephemeral. It is easily altered and there may be no way to detect that the alteration has taken place. Not only is it difficult to pinpoint what software *is* at any given time, there are few guarantees that software will manifest itself in exactly the same format day after day.

All regulatory systems depend on the existence of centralization of information concerning production (e.g., registration of all producers). Software is, of all the medical devices, probably the most decentralized in production. Responsibility is extremely diffuse. In the case of large medical software packages, the attempt to hold a manufacturer liable is frustrated by the fact that there is no single manufacturer in the conventional sense; instead there are a multitude of software programmers at various levels. At the very least we need to acquire new or more suitable working definitions and concepts to shape our understanding and supervision of software production.

From the technical perspective, the most significant problem is that a standard of acceptability eludes definition. Most regulatory endeavors assume some standard or convention of acceptability; however, the task of meaningfully defining a medical software feature such as error-free code is awesome. Some technicians claim that the only way to define an error-free program is to write it. They claim that no specification is possible. Any attempt to regulate software would have to cope with these and other problems.

COMPENSATION

Compensation is often defined as a free marketplace approach. The concept accepts injury as a given, but insists the consumer not bear the financial burden. Its application to technological development is difficult.

The fault system, generally known as negligence, imposes on the consumer the development risk of a new product. Manufacturers are not liable unless they fail to meet some reasonable standard of care imposed by society and sometimes by the government.

A no-fault system shifts costs elsewhere. Someone other than the consumer bears the burden, usually either the providers of a product or the government. In Sweden, all medical injuries of any sort are covered by a government-sponsored/industry-paid-for fund. Although this fund pays all injuries, a company especially egregious in its action can be assessed by the government for greater contributions to the insurance fund.

The most Pareto optimal approach is strict liability on the part of providers, meaning that injuries to consumers are factored into the cost of production, and that the price of the product reflects these costs. In the long run, society receives an efficient level of safety and might be heard to make strong arguments on behalf of this approach since it also preserves some equity. Nevertheless, strict liability harbors a number of practical obstacles. The "deep-pocket" problem, where people with the most money end up paying, is particularly nettlesome. Secondly, and more germane to software liability, the requisite proof is extremely expensive. Transaction costs, often ignored by economists, may be overwhelming.

Sources of Compensation

One alternative is a government-controlled central fund to which manufacturers contribute. However, in the case of software, many "houses" are extremely small and difficult to find. Another is to

make the hospital the sole defendant. Hospitals are, after all, responsible for most of the equipment and injuries. Thus, the hospitals would not be allowed to segregate their liability and turn it over to the manufacturers; instead, liability becomes an expected cost of doing business which hospitals assume as relatively large and somewhat more efficient cost-spreaders.

One problem is that hospitals are notoriously inadequate at estimating the rate of injury due to system failure. To achieve the economies inherent in a compensation model, they must be able to predict the rate of loss and the more efficient predictors must "profit" from their predictions. This is difficult to institutionalize in most hospitals. They are not cost-conscious, and often lack the technical ability to predict losses.

CONCLUSION

In choosing between compensation and regulation, we must recognize that society has an interest in the development of this technology, since it represents a substantial possibility for better health care at lower cost in the future. If the risks of financial uncertainty are too great, the technology may not be developed.

Our current regulatory and compensation systems are unable to deal completely with the problems presented by modern-day medical software. We have not, as yet, encountered the widespread injuries attributable to computer software failure which trigger public awareness and the demand for redress. We may have a brief grace period, but not much. The devising and choice of an appropriate strategy for ensuring software safety and efficacy deserves much more attention than it has received to date, or we can stifle the technology through fear or overreaction to the inevitable problems.

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ZUSAMMENFASSUNG

Schadenersatz oder Regulierung – Das Problem der Benutzung medizinischer Informatiksysteme (*Medical Computer Software*). Gesellschaften, die die Auswirkungen von technologischen Entwicklungen zu kontrollieren versuchen, haben normalerweise zwei rechtliche

Kontrollmöglichkeiten zur Hand, nämlich Ersatz und Regulierung. Schadenersatz internalisiert die Kosten einer schädigenden Handlung in das Unternehmen, das diese Handlung verursacht. Regulierung beinhaltet eine direkte Kontrolle der technologischen Entwicklung. Diese zwei Mittel werden benutzt, um drei gesellschaftliche Ziele zu erreichen:

1. Ein effizientes Produktionsniveau,
2. eine gerechte Aufteilung von Kosten und Nutzen einer technologischen Entwicklung,
3. indirekte Unterstützung bestimmter Technologien, um ihre Anwendung zu fördern (etwa durch eine Haftungsbeschränkung).

Medizinische Computer-Software stellt ein vorzügliches Beispiel dar, um die Schwierigkeiten der Übertragung rechtlicher Prinzipien auf sich entwickelnde Technologien darzustellen. Wenn das Ziel, medizinische Computer einzusetzen, erreicht werden soll, muß sich die Gesellschaft für eine sinnvolle Mischung von Effizienz, Gerechtigkeit und indirekter Unterstützung entscheiden. Auf der anderen Seite sind die der Gesellschaft zur Verfügung stehenden Mittel, nämlich Regulierung und Schadenersatz, nicht gut geeignet, um medizinische Software zu kontrollieren.

Es gibt zwei Arten von regulatorischen Systemen. Das eine besteht darin, daß Erlaubnisse oder Berechtigungen vom Staate erteilt werden, um eine bestimmte Tätigkeit auszuführen. Ein anderes System beruht auf Überprüfung und Inspektion, in welchen der Staat diejenigen Subjekte kontrolliert, die eine bestimmte Tätigkeit ausüben, um zu sehen, ob diese Tätigkeit den sozialen Verhaltensgeboten entspricht oder nicht. In beiden Fällen benötigt das regulatorische System (a) ein bestimmtes zu regulierendes Ziel und (b) einen spezifisch anzuwendenden Maßstab.

Beides existiert jedoch nicht im Fall von medizinischer Software. Software stellt sich als unkörperlich dar, kann leicht verändert werden und kennt keinen allgemein akzeptierten Maßstab. Es kann daher außerordentlich schwierig in ein regulatorisches System gepreßt werden.

Auch Schadenersatzsysteme haben erhebliche Schwierigkeiten. Es muß eine Unterscheidung gemacht werden zwischen Haftungssystemen, die auf Fahrlässigkeit beruhen und deshalb Entwicklungsgefahren dem Konsumenten überbürden, und Systemen von Gefährdungshaftung oder Haftung ohne Verschulden, die Entwicklungsgefahren auf jemanden anderes als den Verbraucher verlagern. Auf der einen Seite können rechtspolitische Gründe für eine Gefährdungshaftung ins Feld geführt werden. Auf der anderen Seite gibt es jedoch praktische Probleme. Die Verwirklichung des Zieles einer gerechten Schadensverteilung kann erhebliche Transaktionskosten verursachen, um herauszufinden, welche Verbraucher durch welche spezifische Software geschädigt worden sind. Noch wichtiger ist das Argument aus Effizienzgrundsätzen, das fordert, daß Produzenten und Leistungsträger die Kosten für die Schadenserstattung sinnvoll den Produktionskosten zurechnen. Dies würde eine effektive Risikoanalyse von den Krankenhäusern verlangen, obwohl sie häufig nicht kostenbewußt arbeiten.

Eine Gesellschaft, die zum Zwecke der Nutzung von Technologien die Entscheidung zwischen diesen Maßnahmen trifft, muß abwägen zwischen Effizienz, Gerechtigkeit und indirekter Unterstützung, wobei gleichzeitig unterstellt wird, dass die rechtlichen Maßnahmen, nämlich Schadenersatz und Regulierung, dieser Technologie nur wenig gerecht werden. Wenn sich die Gesellschaft der rechtlichen Restriktionen nicht bewußt wird, kann sie neue Technologien unterdrücken und abwürgen.

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Mr. VOLKMER. And therefore we do not really need FDA regulation.

Professor BRANNIGAN. Not of the type that they're suggesting. As I said, registration of such systems, I think, might be in the public interest, but not regulation.

Mr. VOLKMER. But not for them to evaluate it and determine whether or not it's a perfected instrument.

But just turn it around and go one step further. With the strict liability, what does it do as far as those who are providing these systems? Are they going to put them out there. Is there strict liability connected with them?

Professor BRANNIGAN. This is where my argument—and this is probably extremely depressing to a lot of people in the health care system—is that that liability ought to be imposed and not be delegable on the hospitals using the system.

In other words, this would allow small providers to compete with large providers because the financial viability of the provider, as opposed to, let's say, their expertise, would not be critical in their ability to put the systems out and that the hospitals that use the systems have the best control over this line between the advice to the physician and being relied on by the physician without further checking, and since that is the critical issue, I believe I would impose the liability on a nontransferable basis on the using hospital or other institution, and that would generate competition in the supplying of these items.

If you will, to use an analogy, this is the way the U.S. Government operates in the acquisition of a lot of its products. By accepting the liability itself, it opens up the competition to supply those products to the widest range of potential producers.

Mr. VOLKMER. As I read the statement, by the way, from FDA, it is almost like they are saying that on software—they have under the heading here "Stand-Alone Software"—that they are possibly proposing to regulate it because of this software.

Professor BRANNIGAN. I read it the same way, and, as I said, I think proof by blatant assertion is the logic they're using.

Mr. VOLKMER. And what bothers me, just using their definition—I'd just like to read it in. We will insert the statement into the record in full. But it says,

> No separate policy for computer software presently exists nor is one envisioned for the future. Medical software products

And they use the word "products"—

> That are marketed separately from a computer (generally referred to as "stand-alone software")

So now I'm talking about the floppy disk; it has the Caduceus information or any other one on it—

> And used with a computer to form a system which operates as a medical device will be treated as a medical device.

Now you're saying it's blue because it's blue.

[FDA's statement appears in app. I.]

Mr. VOLKMER. Now what bothers me a little bit with that is, I have a physician out here, or hospital, that has a computer system, and just because it's a computer system, let's say right now all it's

doing is basically information gathering on patients and storing. That, in itself, is not a medical device, is not under FDA regulation.

The way I read it—and I ask you, Professor Brannigan, if it says the same thing to you—I buy the same floppy disk and I put it in the computer, and all of a sudden that whole system has to be regulated.

Professor BRANNIGAN. If I can extrapolate on this just a little bit at length, in my conversations with them, that is the way they talk—that is, speaking broadly of FDA people at various levels, realizing that no one speaks for FDA except the Commissioner, and all those kinds of limitations.

Mr. VOLKMER. Right.

Professor BRANNIGAN. I think they're people of immense good will and want to do the right thing by consumers. I don't think there's the slightest suggestion that they are not acting in what they conceive to be the public interest, as well as that can be established. I think they're just wrong.

I think that their idea is that this is some kind of new bedpan, that it's a thing, and their attitude is oriented toward it as a thing, as a product, if you will, and having made that at some preliminary stage, then they're wrestling with the fact that it's very hard to mesh this very strange thing in with the rest of their other things. So, rather than try to create a separate regulatory program, they just say, "Well, we're going to treat it the same as all the other things."

However, in oral conversations they have said that people who use artificial intelligence systems who provide advice to hospitals are in the service business and they're not going to regulate that. So it's even worse than what you're describing. If you buy the floppy disk and put it in your hospital, they'll regulate it, but if somebody in Canada buys the floppy disk and tells you over the phone what it's doing, it's not regulated.

So their position is simply not logical. It doesn't bear any resemblance to logic, and I think that the ultimate answer is simply that you go back to the statute, that they don't have jurisdiction, and I base that really on three points in my other paper. One is that the statute just says "contrivance," which isn't an idea—which is what Caduceus and the rest of these other systems are; they're ideas. Second, the legislative history doesn't support that broad a reading; and, third, the constitutional issues.

I mean, these are fundamentally ideas, and in the very first interpretation of the Food and Drug Act in 1911 by Justice Holmes, the Congress didn't mean to regulate people's opinions as to what was right and wrong, they meant to regulate certain specific devices—I have that cite,[47] if people want it—and I believe that that has carried down to today.

I've got various books with me of lunatic medical theories—of all sorts of books you can buy in the supermarket, and whatever we do in this country, we don't regulate people's lunatic medical theories, whether they write them in books, or put them in Dr. McDonald's

[47] *United States* v. *Johnson*, 221 U.S. 488 (1911).

system, or whatever. We don't regulate that because the Constitution says people have certain rights to their ideas, even if they're crazy, and I've cited a few of these cases in my material.

So, therefore, I think the FDA is trying to regulate something in which there is no track record of being able to effectively regulate it, which is why they produce last-minute statements, because even in the best of faith, with the best of will, the best of technology, the best of intentions, they can't do it, and I think they've admitted on numerous occasions they have no standards against which to measure these things, and I think what that just indicates is that it's not the kind of thing that the medical device regulations were designed to control.

Mr. VOLKMER. To go one step further, what costs would you envision would be imposed on a total health care system if they proceeded with this type of regulatory policy?

Professor BRANNIGAN. I think it's in the form of opportunity costs, as the economists would call them, which is, you'd stifle the industry.

Mr. VOLKMER. In other words, it does away basically with what we're trying to do.

Professor BRANNIGAN. In my limited experience in talking to the people, these systems have been built in the equivalent of basements by people on—despite what looks in numbers like generous Government funding, compared to various other areas—these things have been built on a shoestring, and they're implemented on very small computers, and they perform wondrous things on nothing. We really are dealing with an infant industry.

I will say an analogy that I use, however—in terms of long-term power, and particularly interaction with the doctors, which I use in the materials—is this is John Henry and the steam drill.

In other words, we've got the first steam drill, and right now there's no question that Dr. McDonald can personally smack his own computer system down, but they don't forget, and they do get better, and as you get the collective efforts of lots of people, these systems will, over the next few years, have the potential of rivaling—not necessarily exceeding—in ordinary diagnosis the capabilities of the vast run of doctors; I'm convinced of that; and that's why stifling that potential, and not only its potential for the United States but for other countries which don't have our medical surplus, I think, would be a real loss, and I think that the FDA proposal has that potential, to simply wipe the whole industry out.

Mr. VOLKMER. Dr. McDonald, do you share Professor Brannigan's optimism for the potential for these type of—we won't call them medical devices; we'll call them computerized informational systems, diagnostic informational systems.

Dr. MCDONALD. Well, I share his enthusiasm about what he says about the regulation side of it, and I don't want to pretend—I'm a computer nut. I practice, see patients, but I do like computers, and I work with them a good part of my waking hours, but I think that we must not—and maybe I'm overreacting a little bit—we must not dramatize too much their power.

I don't disagree—they're smarter, they can save more information, they can do things more accurately—but what they can't do is

see the patient (yet), and there's an immense amount of redundant information in that process, you know.

EKG [48] [electrocardiograph]—we've had analyzers that sound the bell when the patient's arrested since 1955, or 1965, anyway, and at the beginning, they always sounded—mostly when the patient was still alive and well, and I have never yet even heard of an instance where one of those computer alarms went off and, if the patient was eating or talking, someone rushed in and shocked them. You know, we [physicians] just kind of [49] see that, and in an instant we just discard all the other rules, and as long as the computer looks at it [the patient] through a little peephole at what data happens to have come in through sensors, I think it's prone to being very dumb, and you're going to still want someone sitting there.

You're going to want a pilot flying that plane even though it's got an automatic pilot that's very, very, very smart. You still have two pilots up in that 747—or maybe three, I guess it is now—and I think you're going to want that for a long time.

Now there may come a time when computers—and this is many orders of magnitude beyond where we are now—can sort of do a Dr. [Mr.] Spock sort of thing [50]—they point something at you and really see the whole patient in all of its glory through NMR [nuclear magnetic resonance] or some such thing—and be equivalent in the total spectrum of knowledge of the physician. But the physicians may not know as many facts, but they know more about the patient than the computer will in a long, long, long time to come, just by a glance.

Mr. VOLKMER. All right.

Professor Brannigan, I'd like to get back again just a minute to the—before I do, Dr. McDonald, what you're telling me is that it may occur in the future but right now you don't want to raise the optimism to where everybody thinks this is going to happen tomorrow or next year and we really don't need the expert physician any more, we're going to have him in one computer. We're still going to have to have the physician.

Dr. MCDONALD. We're not at a watershed.

Mr. VOLKMER. Right. OK.

Professor BRANNIGAN. If I may, for the record, I don't disagree that that's the current status.

Mr. VOLKMER. Current—right; 20 years from now or 25 years from now, we may see something a little different.

But on the strict liability question, how would you apply that, basically, to an operation such as, without designating as, but such as that which has been described at Disciples Hospital—Latter-Day Saints—excuse me—Latter-Day Saints in Salt Lake City?

Professor BRANNIGAN. OK. If they send up a record from the laboratory and it's wrong, either because it's wrong because someone

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[48] Dr. McDonald changed "EKG" to "Consider heart monitors . . ."

[49] Dr. McDonald asked that "kind of" be deleted.

[50] Dr. McDonald alludes to the futuristic medical technology portrayed in the syndicated television series "Star Trek (©Paramount Pictures). The chief medical officer aboard the fictional U.S.S. *Enterprise* was Dr. Leonard McCoy, however. Mr. Spock was first officer and science officer aboard the *Enterprise*. Examples of the technology can be found in the *Star Trek StarFleet Technical Manual* (New York: Ballantine Books, 1975) and the *StarFleet Medical Reference Manual* (New York: Star Fleet Productions, Inc., 1977).

entered it wrong, the computer stored it wrong, or it comes, and let's assume causation and all those other good legal things—you know, that the wrong data—all of a sudden it comes up with this wrong data, and someone shoots the wrong medication into the patient or something like this, I would essentially impose liability without the plaintiff having to prove why the wrong data was provided.

In other words, strict liability, to me, is you have to prove causation, but you don't have to prove a violation of a standard of care, and it's that simple. In other words, you have to prove, in effect, not that the patient was harmed, which is the first step, but you have to prove that it was caused by a defect in the system.

The difference, as I interpret it, is the difference between having to prove a failure to meet a standard of care, in which case we'll talk about what a reasonable computer system would do. Strict liability would say, "It's got to be right when that information comes up."

Now let's assume that the information, for the moment, is probabilistic. The concept of rightness of information when it comes with a probabilistic conclusion, this is an area that I'm still researching, and I don't have as clearcut an impression.

That's why I think there is this critical difference between data which you rely on without further analysis. I mean, if we put a thermometer in you and it comes up 105 and your real temperature is 98, that's strict liability—that data output—and that's where, I think, the strict liability would come down.

I'll give two minor analogies. A lot of hospitals—I promised confidentiality, incidentally, when we talk about privacy—to everyone who gave me information about the failures of their own systems when I was conducting this research, but at one major hospital where they had a stupendous backup system—I mean, running seven computers simultaneously—they had the shop for repairing terminals directly connected to the computer room without any fire safety. In other words, they had thought about patient privacy, a lot of other issues, and ordinary fire safety, and the loss of an ongoing ICU, and everything; they had seven simultaneous processors, and they could burn the whole thing up with a match. You get these kind of technical blinders that people get into.

Another issue, to use an example from the privacy, is that 1 hospital with 64—a very prestigious hospital—with 64 different computer systems in operation, full blast, going all the time, only 1 was encrypted and password protected, and that was the physicians' salary system, which indicates that when it really gets down to something critical for privacy, physicians don't mind the interference with their doing business.

Mr. VOLKMER. But basically, on the Caduceus system, which is basically an information system now, even though it would be, let's say, a diagnostic system along with it, helpful in recommending diagnosis to a physician, the physician using that would still be under a negligence standard.

Professor BRANNIGAN. I believe it would be under negligence standards if for no other—I think there are multiple reasons that that device doesn't really reach the patient, as required by section 402(a) of the Restatement of Torts. It doesn't reach, and that reach-

ing requirement in this area is really very important, and it is filtered, and I believe the negligence there would be at two levels. One is, was the physician negligent in relying on the system? Second, was the system negligent in handing that information to the physician? And I think we have drawn that distinction in our environment.

Mr. VOLKMER. It would be the same thing as with the type of computerized system that Dr. Gardner has described. If the computer failed to find a drug interaction and a nurse, along with the doctor's prescription for it, gave the drug and there was a severe interaction, that would be strict liability, would it not?

Professor BRANNIGAN. I would say that would be strict liability.

Mr. VOLKMER. All right. Where are we then with the hospitals on insurance—in other words, trying to get insurance with this strict liability?

Professor BRANNIGAN. OK. When I talked with the major medical centers—now the centers that I dealt with were overwhelmingly academic medical school medical centers—a vast number of them are, in effect, in the self-insurance business because their risks are uncalculable, and many of them buy coverage with $1 million deductibles.

In other words, they're really insuring against unbelievable catastrophes, and the rest of the time they rely on very careful monitoring of risk—I think this is very important because this is where we place some of our students—but very careful monitoring of risk within their own institution and watching it, and I think that this creates a better level of care.

In other words, internalizing regulation is much more effective than external regulation, but hospitals tend to buy insurance in a very, very competitive—they're big buyers in the market. Therefore, the crises that come tend to be crises of overall coverage, not the kinds of crises that come with relatively small purchasers like day-care centers.

So, yes, there is both a malpractice insurance problem—I don't know if I want to call it a crisis—but I think hospitals—I have not heard from these hospitals that insurance coverage, as such, for their broad operations—they don't tend to buy coverage for narrow, little points of their operation, they tend to buy all-risks coverage, and they tend to have very large deductibles, in my limited experience. Someone else could correct that, I'm sure.

Mr. VOLKMER. All right. How would you propose to impose the standards for strict liability in one instance and negligence, which is present law, on the other? Statutorily, or just let the courts——

Professor BRANNIGAN. I think a common law analysis would be adequate for this purpose, because we rarely would get into some of the more complex areas of assumption of risk and contributory negligence.

I don't believe it requires any statutory development, and it has the minor advantage that the hospital knows what legal system it's operating in under its State law, whereas you don't get that national problem of products which move in interstate commerce and what are the different rules.

So you actually negate some of the national commerce problems by imposing liability on a thing where you can say the law applies here because this is where the patient comes from.

Mr. VOLKMER. OK. Have any of you—again, as to the previous witnesses, I want to ask this—ever been asked to serve on any of the FDA advisory panels on this subject or the subject on which you testified?

Mr. BELAIR. No, sir.

Mr. VOLKMER. No. Dr. McDonald—Professor Brannigan.

Professor BRANNIGAN. I say this—I'm not sure they ask lawyers routinely ever, so—but I will say that I have been asked to serve on an advisory panel to NIH in some related areas, or at least reviewing grants or something.

Mr. VOLKMER. Dr. McDonald, have you ever been contacted at all by the FDA on expert systems?

Dr. MCDONALD. Well, I was invited to the AAMI meeting last weekend in this regard, and—yes, I guess.

Mr. VOLKMER. But that's been the only interaction.

Dr. MCDONALD. Yes.

Mr. VOLKMER. And it's been very recent.

We've heard Professor Brannigan's feelings and, I think, to some extent, yours, Dr. McDonald, but I would like you to, if you would, specifically address bases for FDA policy or proposed policy in regulating medical software, and some of that is—again, in their statement they said it's inherent public health risk of products—inherent public health risk. How would you assess such risk since you propose—and I believe still we will have the doctor in between—how do we——

Dr. MCDONALD. I think it reflects maybe a negative understanding of the physician's operational behavior. I look at physicians as being the most cynical about others' opinions, the most untrusting, and compulsive of human beings in many—for many different categories.

You know, as a faculty member, I tell the residents, "This is what you ought to be doing." They go, "That's crazy; I don't believe that." They're willing to reject anything—I mean, not that mine may be the very best, but they certainly are not at all reluctant to discard advice from others or others' observations. The tendency is always do it yourself, check it yourself, and believe your own observations, and there's an immense redundancy in the process.

I don't think just because—and we have some little inklings of how the decision process works, but I don't think we have a deep understanding of many human decision processes, but there's an awful lot of redundancy in it, and we do give computer reminders, and the residents and faculty accept them. They don't love them, although they behave remarkably different with them—and one that they took great glee—and they're error prone.

I rather would say there's a sensitivity and a specificity, just like a test, and when you do a mammogram, you get a positive test result. You're only right one out of five times. That is, most of those positive cancer-looking mammograms will actually be noncancerous when they're biopsied, but we don't consider that an error. So you have to make these tradeoffs, and you operate where the balance falls out right.

Well, we had a reminder to do a cervical Pap smear, which is one of the preventive tests, and it was on a patient who had the code of M—I mean of F, for female—stored in their sex field, [the patient] but it was a male, and—but there was not even one single attempt to do a Pap smear on that man. They didn't even call the nurse to get the equipment. I mean it was just—but that's the kind of thing. It's just blatantly obvious, and so instead, what they did, they Xeroxed ™ that record, and they papered the room with it. They took great glee in finding the mistake by the computer, which did what it should do—respond to that field and say something.

Even in due respect to this fever issue, if I gave you a thermometer and it said you had a 105° temperature, I'd go feel your head, just like your mother did, and I'd go: "No, that doesn't make sense, because you don't look sick." I mean, there's all this other information you get.

So I think that there is not a grave risk. I think there's got to be thought given to it. I think there's got to be more products out there and more experience to understand whether there are problems and what they will be.

Mr. VOLKMER. OK. I'll now yield to the gentleman from California for his questions.

Mr. PACKARD. Thank you.

May I continue just a little bit with Dr. McDonald on the point you were just talking about, confidence that physicians have in other physicians or other opinions.

Do you think then that physicians, as this kind of an expert system would be implemented, would have more confidence in a computerized informational system than they would in the consultation process with each other?

Dr. MCDONALD. It has not been my experience, and my prediction is, in fact, until these systems are very, very good, they'll be used relatively infrequently.

Mr. PACKARD. You are rather pessimistic as to the quickness that this kind of a system will be implemented.

Dr. MCDONALD. Well, it's based on history. The system developed by Howard Bleich for acid-base balance was not developed with LISP or the classic artificial intelligence approaches, but it produced a consultation. It was very accurate about acid-base problems.

They put it in 30 VA hospitals, and they ran it for 1 year, and basically no one came to the wedding feast. Of course, they had to go upstairs to go to the terminal, had to learn how to use the terminal; there were all the problems about interface, and socialization, or other kinds of issues, but it is not something that I think is going—is a vast market immediately available.

I think where the power is going to come is in systems like the HELP system where the computer volunteers [information] without an investment by physicians, and they get information, and not only does that give them—that gives them two things; it tells them when they don't think to know there's a problem.

You see, if you have to say: "I think there's a problem; I'll go ask about it," you don't get as much advice[51] as if you say you haven't

[51] Dr. McDonald changed "advice" to "help."

thought about it, and the computer says: "Hey, there may be a problem." Samuel Johnson said man more often needs to be reminded than informed, and I think—that was a long time ago; I think it's still true.

Mr. PACKARD. It would appear to me that if Dr. Myers is correct as likening this unto a computerized textbook, it becomes then a refresher tool of information that the physicians may have gotten over their studies and their experience but have not—their recollection of the processes simply aren't able to recall all of the information that they've had available to them. This becomes a recalling or a reminding tool. It would appear that that would tend to be more of a confidence builder than perhaps consulting with someone else that may have forgotten even more than what you've forgotten.

Dr. MCDONALD. Well, I think it will be very useful in that respect, that is, to restructure your thinking and re-remember the things you do, and maybe even to guide you to ask some other questions.

But you have to remember the advantages the human consultant provides. This is not to diminish the system, which is a very exceptional development but, rather, to maybe enlarge the human capabilities.

If you have a human consultant, No. 1, you just have to call them, and then you're done. No. 2, you've got protection in terms of malpractice and he may have a bigger bankroll than you have, if he's one of the right kind of consultants. No. 3, he goes and gets other observations, and as we're taught in medical school, that's often the biggest value of the consultant. It's the thing they felt when they feel the thyroid that you didn't feel, or it's the history they dug out that you didn't dig out; it may just even be in a redundant gather.

So we need to emphasize this information gathering; if you talk to the consultant computer, you're the one that gathered the information, and you filter it for the computer, and so you don't get as much, I don't think, as you do out of an expert consultant at today's history;[52] 10 years from now, it might be quite different.

Mr. PACKARD. Before I forget, Mr. Chairman, I intended to ask unanimous consent to have the response that Professor Brannigan has mentioned in regard to this recent document entered into the record also.

Mr. VOLKMER. Yes.

Mr. PACKARD. I do not have a copy of your response, and so before we leave today, I'd like to get it.

Professor BRANNIGAN. I gave it to Mr. Paul [James Paul, professional staff member, Subcommittee on Investigations and Oversight], I believe. Here's another copy.

Mr. PACKARD. Fine.

[The document follows:]

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[52] Dr. McDonald changed this to read ". . . an expert consutant . . . today."

THE REGULATION OF MEDICAL COMPUTER SOFTWARE AS A "DEVICE" UNDER THE FOOD, DRUG, AND COSMETIC ACT

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Abstract

Recent developments in medical computer software have raised the possibility that federal regulators may claim to control such software as a device under the Food and Drug Act. The purpose of this paper is to analyze the statute to determine whether computer software is included in the statutory scheme, examine some constitutional arguments relating to computer software and finally to discuss some regulatory principles which should be taken into account when deciding what type of regulation might be appropriate. This paper is limited to computer programs whose output is used by humans in deciding what medical therapy, if any, a patient should receive.

Statutory Issues

The 1976 amendments to the Food, Drug and Cosmetic Act (FDCA) extend federal regulations to medical devices. Devices are defined as:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- ...

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals..." FDCA 201(h)

The act sets up a series of classifications. Devices are divided into Class I, II, and III. Class I devices are subject only to the most general manufacturing controls. Devices under Class I include bedpans, skull punches, crutches and stethoscopes. Class II devices are subject to more stringent performance testing. Class II devices include the bulk of medical devices including fetal monitors, heating pads, spirometers and therapeutic genital vibrators. Class III products are subject to the most stringent controls, including premarket approval based on appropriate tests. Class III devices include: intra-uterine contraceptive devices, intra-aortic balloons, pacemakers and replacement heart valves. Currently computer systems are not classified under the act. However, they could be placed in either Class II or III, depending on the FDA's interpretation of certain provisions of the statute. Certainly, if medical software is placed in Class III, the cost of regulatory compliance will be enormous.

The first question is whether clinical medical software is or can be a device under the FDCA. There are basically three approaches to statutory analysis. First, the actual words of the statute should be analyzed, to determine exactly what Congress said. Second, the legislative history of the statute can be examined, to expand on and explain the words of the statute. Third, the administrative agencies interpretation of the statue and its regulatory program can be analyzed to determine whether a given interpretation is reasonable.

Statutory Language

The most obvious problem in trying to apply the statute is that computer programs do not fall clearly into the category of "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article." Clearly most of these terms cannot apply to programs, since they refer to a specific tangible item. Software is intangible, somewhere between an idea and the expression of an idea. The only word which could apply to software is "contrivance." Contrivance is an ambiguous

term, which can apply to a machine. It might be argued that anything developed by man could be a contrivance, however, the word appears in a list of other words which all apply to tangible items, and which is followed by the term "and similar or related article." This would tend to negate any inference that contrivance refers to some kind of thing which is wholly different from the remainder of the list of items.

Computer programs are significantly different from the other types of medical devices regulated by the FDA. While a computer driven device would clearly be tangible, computer programs themselves are abstractions. They are a species of intangible property, whose value is extrinsic. They can exist in infinite numbers and each one is identical to the original.

Tangibility of the software is not just a minor feature, it relates to the fundamental nature of computer systems. What distinguishes computer programs from medical devices is the lack of any need for a specific physical entity. When a physician sits down at a computer terminal, the machine can be on the desk, in the basement, or in Canada. It makes no difference to the user. No other product in the area of regulated medical devices has this characteristic. This is significant because the FDA has already described the provision of computer analyzed data to a hospital as an unregulated service. What difference does it make where the computer is located? What about analysis conducted in another country?

It is worth noting that the treatment of computer programs under other laws has depended heavily on the issue of tangibility. Computer programs cannot be patented, because they constitute algorithms. Computer programs can be copyrighted, but only as the expression of an underlying idea. Computer programs are "goods" under the Uniform Commercial Code, but the code has no requirement of tangibility. Computer programs may be products for liability purposes, but that is in spite of their intangibility.

At the very least, therefore, the statute is ambiguous and contains no clear authorization for the FDA.

Legislative History

Legislative history includes the various debates and committee reports which led up to the passage of a statute. It should be noted that it is not sufficient that a device should be regulated. The critical question is whether congress meant for FDA to have jurisdiction under the act. Since clinical medical computer software was virtually non existent in 1976 when the medical device amendments were adopted, there is no specific legislative history to use to see if the congress meant to include it under the statute, and if it was under the statute, which classification is justified. The lack of a specific legislative history is not fatal to the regulatory process. Congress often sets up agencies for the specific purpose of dealing with new hazards as they arise. In the case of medical devices, the most important inquiry into the legislative history is whether congress intended the medical device amendment to close a gap completely, or whether they were designed to bring a specific set of products under FDA jurisdiction. The history is at best inconclusive.

Agency Interpretation

The FDA is an extraordinarily expert agency in an unusually complex field. This means that decisions of the agency concerning its own jurisdiction are likely to receive great deference in the courts, if supported by a possible reading of the statute and reasonably consistent regulations. However, if it appears the agency is having difficulty articulating a coherent regulatory program, the courts may interpret that hesitation as indicating a lack of expertise in this particular area.

The FDA has not yet articulated an official position on the regulation of software. Part of the problem is fitting computer software into the other requirements of the statute. The statute is product oriented. It refers to manufacturers and good manufacturing practices. It assumes that the output of the manufacturing process is a specific item, which can be counted, labelled and shipped. The entire concept of the statute is foreign to the world of computer systems. Intangible items are not manufactured. Computer systems are not standardized items, and even similar systems have crucial differences. Software is ephemeral; it is often changed in the field by users, and can be altered without trace. A program is often the product of many hands, who leave no trace of their

individual efforts.

Programs do have characteristics which would tend to make them regulatable despite their intangibility. Computer programs can be owned, they exist through time, they have errors, which can be corrected. They can be passed from person to person. Like the camshaft on a car, once the instructions are set, the machine will do what it is told. However, the term device may be a narrower concept than product.

The sum total of any analysis of the legal status of computer programs under current law is inconclusive, and may require litigation. Preparation for such litigation must predate any FDA action, since deadlines for appeal to the courts are typically very short.

Constitutional Issues

The existence of a constitutional issue in the area of medical software may appear forced to most people, since medical care, pharmaceuticals, and medical devices have been regulated for decades. However, the very intangible nature of computer software may bring it within the reach of the first amendment's protection of the freedom of the press. The suggestion is that a computer program constitutes the author's ideas, and that ideas are absolutely protected under the first amendment.

This defense was successful in the related cases of SCIENTIFIC MANUFACTURING 124 F.2d 640 (1941) and PERMA-MAID 121 F.2d 282 (1941). In SCIENTIFIC MANUFACTURING an author was selling a book which contained his own opinion that aluminum pots caused cancer. In PERMA-MAID a corporation selling cast iron pots made the same claims. The Federal Trade Commission brought actions against both parties. The FTC prevailed against the manufacturer on a claim of false advertising but lost against the author on First Amendment grounds. While these cases are over 40 years old there is no reason to believe that they are not still good law.

The existence of a constitutional issue may make a court more hesitant in giving an agency jurisdiction over the area, since congress is not assumed to readily commit to an agency the power to regulate activities subject to the first amendment.

Policy Issues

Whatever decision the courts might make on the purely statutory issues, it is important to define the policy issues involved in the regulation of software. It can be assumed that the goal of any such system is to promote the advancement of medical technology while maintaining the maximum of patient protection, both physical and financial.

The primary question in both areas is what legal approach should be used to control clinical software? The problem with the FDA's approach is that the product oriented standards of that act would be both ineffective and hostile to the development of the technology. The legal system should not attempt to define in advance what direction this technology will take.

Computer systems are a completely novel technology in medical care. Trying to fit them into regulatory systems designed for other technologies will inevitably both slow and constrict their developments. In the absence of a clear danger from the system this is unwarranted. A product oriented regulatory system may be detremental to the entire medical software field. Computer programs are not built to blueprints. They are built to a system design which is normally changed continuously as the system is being installed. Many are one-of-a-kind installations where the design, production and quality control phases are merged together. Systems are often created in joint efforts between medical users and software houses. Systems are often put into service for field testing despite the presence of errors. Sometimes testing the system does not reveal defects; only prolonged use of the system will. Since error correction is labor intensive, it is typical to leave a certain number of "bugs" in any system, to be corrected, over time, as the system is used. The term "maintenance" which in most fields is simply keeping the machine up to specifications, is used in the computer field to describe this continuous error removal process. Because of this process, there may not be the clear cut separation between manufacturer and user. This reality must be taken into account.

There are certain basic principles which should control all legal efforts in this area.

First is protection of patients from the unreasonable risk of injury. Second, there should be a search for relative improvement in medical care, not absolute perfection. Third, any system should avoid entrenching existing institutions, whether governmental, industrial or professional. Fourth, in any implementation of a computer system there must be a financially responsible party. Fifth, in terms of patient therapy there must be a party clearly responsible for the proper operation of the system.

Compliance with these principles is difficult under the current legal system. Under the current regulation of medical devices and drugs, the federal government controls the manufacture and labelling of devices and drugs, and the states control the use. For all of the reasons I mentioned earlier, the technological development of this field has made this distinction between the product and use of the product obsolete. For example, a hospital worker sits down at a terminal. It makes no functional difference whether the computer is located in the same hospital, across the country, or in another country. Likewise, it makes no difference whether the system is produced in his hospital, or purchased on the outside. It is of no importance if the system is one of a kind or one of a group. Yet both the regulatory and liability systems fasten on these irrelevant distinctions to impose widely different levels of regulation and liability.

The primary policy choice is between the product oriented concept of the current medical device legislation act, and a user oriented regulatory approach suited to the nature of this technology.

The major problem with the product oriented approach is that it tends to stifle all of the attributes which make computer software such an exciting technology. Product oriented regulation tends to limit developments in a field to those companies which are both adept at the technology and sophisticated in dealing with the regulatory authorities.

Second, product regulation tends to centralize production in a small number of firms. The first handful of firms approved can divide up the market because regulatory approval is a substantial entry barrier. There are only a small number of viable hardware producers in the computer field, compared to the vast number of software houses. This is due to the different economies of scale in starting up operations. The regulatory burden could be crippling to small, innovative companies. It is precisely these innovative companies which are the strength of the computer field. Many of the most innovative producers are universities and hospitals. There is a tradition of sharing breakthroughs and software, which could disappear due to regulation.

Third, regulation of the software tends to limit the flexibility of the user in adapting the device to local conditions. While the FDCA provides for customization of a device to a patient, it does not provide for customization to the institution, which is often critical in clinical software. Moreover, modifications of systems by producers in light of system failures or increased knowledge would be slowed by the need for regulatory approval.

Fourth, under the current concept, liability for defective software is diffuse. Small companies may not be financially viable. Insurance in this area is becoming unobtainable. The liability exposure is determined by traditional strict liability with contractual disclaimer and indemnity.

Fifth, some software will be exempt from regulation, because it is created by the using hospital. Software can also disappear from the regulatory system because of the demise of the producing company, while the software is still in use.

Sixth, at the current level of software development and use, a form of registration combined with the possibility of inspection is probably adequate to protect consumer interests. There are strong forces in the hospitals to guarantee accurate and reliable data, forces which have been adequate to the present to prevent known injury.

These deficiencies can best be addressed by recognizing that software is a fundamentally different item from a scalpel or an x-ray machine. One possibility would be to adopt a regulatory system oriented towards the user of the software, usually the hospital, rather than the producer. Such a proposal would involve registration of each

user location.

This proposal would have the following effects: 1) It would focus regulation on the parties actually controlling the use of the software. It would clarify responsibility for control of the software and the potential uses to which software would be put. 2) Liability would be imposed on the using hospital, as the place best able to evaluate what level of oversight is needed. By concentrating liability at the user level there would be an increase in competition, rather than a reduction, since the financial viability of the producer would no longer be an issue. 3) The users are already subject to regulatory control. They are familiar with the requirements of the regulatory authorities. 4) Hospitals are large enough to self-insure this risk, or they can purchase broad insurance coverage at market rates.

Conclusion

It is arguable whether software is a medical device under the current Food, Drug, and Cosmetic Act. However, in the long run medical software should not be exempt from regulation. In the case of this unique product, the public interest would be best served by imposition of a modest level of regulation on the user. This would provide the optimum mix of protection of consumers with minimum restrictions on the development of this revolutionary technology.

Mr. PACKARD. The question was brought up with the first panel as to whether it is anticipated that such systems, expert systems, will reduce ultimate medical care costs to the consumers. I'd like your impressions, particularly Dr. Clements and perhaps Mr. Belair.

Dr. MCDONALD. Well, I think they're the only hope. You know, we have to do—there are two issues. One is to whether you can save dollar costs, and the other one is whether that will be passed on, and I think as the earlier panelist described, the regulatory realities are in place now that if costs are reduced they will tend to be passed on.

It's a competitive environment now, and there are opportunities as there—say the engineering workbench; the physician works at a terminal and can get every answer he wants about facts, about history, about the patient, plus decision support as he goes along. He can care for that patient faster, or maybe a nurse clinician can do a lot of the work in conjunction with the physician, or maybe a pharmacist can do more of the work.

I'm not prejudiced about who does the work, but it seems clear that these systems will save time, immense amounts. My guess is we can save a third of the physician's time flat out within the next couple of years by these kind of support tools, plus do a better job at the same time; we can finally manage the system.

Now that may be against the physician's interests, but instead of having it being sort of a cacophany of everybody doing what they please, someone can look at the whole system and say, "Hey, this is crazy; this guy's doing all these crazy things down here, and people are dying too fast;" or we can put it into some kind of a rational perspective, look at the data, analyze the data, and make judgments based on data rather than on just beliefs and biases.

Mr. PACKARD. Mr. Belair.

Mr. BELAIR. My answer, sir, would be strictly from a layman's standpoint. It does sound as though there's the potential for cost savings. I will say that it continues a process that's been going on for about 50 years now, which is to limit, to deemphasize, the role that the physician plays in providing health care.

Today, I guess you could quibble with the statistics, but the latest statistic that's bandied about is that only 5 percent of health care in this country is provided by physicians, and since they're obviously the most expensive component of the system, to the extent that you deliver health care through other means, you've got the potential for cost savings.

Unfortunately, from a privacy standpoint, there's a downside. Physicians are awfully good at maintaining patient privacy. They're steeped in that ethic. Most of the privacy problems that I've encountered' and I think most of them that are documented, come not from physicians but from other health care providers and professionals who simply don't have that same ethic and that same concern, maybe not as much to lose. You know, you could speculate about lots of different reasons for it, but it seems to be a phenomenon.

Mr. PACKARD. Professor Brannigan, you've talked at length about the liabilities that are related to misinformation or that may come through such a system, malfunction of the system, but we haven't

talked about the time when the lack of use of this kind of a facility would become an issue of liability.

When does a system reach the point where it is moved from a time when you'd be sued for using a system and a system not producing or providing adequate information or not doing what you want it to do, or you're misusing the system? When does it move from that to where you're sued for not using a system?

Professor BRANNIGAN. The traditional term for this type of analysis is Hooper analysis, after a case called the *T.J. Hooper*,[53] which was a tugboat which didn't have a radio in 1928—I'd have to check my dates—and therefore lost some barges because it didn't have the technology, and the court in that case—and there is a little bit of material in my longer written statement—I think Mr. Paul has it—on some of the cases in medical care that have analyzed this issue, that courts can and do say that an entire industry is negligent or portions of it are negligent for failure to acquire and use the appropriate technology at a certain level of certainty.

In my experience, I think we are there in drug-drug interactions. I think that's an essentially clerical technical task where there's no excuse to not have that module working properly even at the level of ordinary pharmacists. I mean, the stuff is very cheap to run this kind of system.

In broader terms, when will the failure to use a consultation—when will the failure to acquire such a system—I don't think in terms of complex expert systems we're there in the next, rough estimate, 10 years, but for narrower portions of it I believe that it's right there right now. I can furnish you with an article by Bruce Watson, formerly up in Massachusetts, that covered this issue that was in our symposium proceedings. I can probably get you a copy of that.

[The article follows:]

[53] *The T.J. Hooper*, 60 Fed. 2d 737, 2d Ct. App. (1932).

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LIABILITY FOR FAILURE TO ACQUIRE OR USE COMPUTERS IN MEDICINE

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Abstract

The traditional legal rule used to measure the adequacy of a provider's delivery of care is the custom of other providers in the defendant's locality. Many courts have expanded the definition of locality, and several recent decisions have adopted the rule of reasonable prudence as the measure of what custom should be. These developments suggest that courts may impose liability on providers for patient injuries caused by the absence of medical computers even where the custom of most other providers would not have required computer use. A judicial finding of liability apart from custom will depend upon a balancing of factors such as availability, likelihood of risk reduction, and cost.

Introduction

"Computers can help the physician diagnose illness and prescribe the best treatment. They can alert him to possible interactions between drugs, monitor patients, perform and enter test results, and retrieve medical information. Where time is critical to patient safety, computers can save minutes, or even hours, in providing a doctor with data necessary to an informed decision."[1]

The purpose of this memorandum is to consider the likelihood of provider liability for injuries caused by the absence of computers in the delivery of health care. Provider liability will depend upon a judicial determination of whether the standard of conduct for the medical profession requires the use of a computer in the medical context in question. The central theme of this memorandum is that the traditional legal rule governing the measurement of a provider's conduct has eroded in several ways, including redefinition of the locality rule and the extension of the concept of "reasonable prudence" to medical care: these trends suggest that courts will sooner or later impose liability for a hospital's or physician's failure to use a computer where its application would have prevented an injury.

Medical Negligence and the Standard of Care

The standard of conduct required of a provider in order to fulfill an imposed duty is usually the major focus of a malpractice action because the standard defines the parameters of duty. That is, the standard of conduct is the measure of care by which breach of a duty is established if the defendant provider failed to provide such care. The traditional standard of conduct which a provider owes to its patients is for that physician or hospital to exercise the degree of care, skill, and diligence used by other providers similarly situated, or what is commonly called customary practice.[2]

The identity of the comparative group has traditionally been drawn from those doctors or hospitals in a provider's home community. This "locality rule" was developed in the context of malpractice litigation involving individual physicians, and was later extended to hospitals.

However, a substantial number of jurisdictions have modified or completely replaced the geographic concept of the locality rule.[3] Many courts have adopted the standard of care that is customary within communities or localities similar to that of the defendant provider.[4] Other courts have expanded the spatial reach of the rule to include nearby communities readily accessible to the patient, in effect recognizing the change in geographical accessibility wrought by modern transportation.[5] Some jurisdictions have adopted and applied a national standard, which often recognizes differences among hospitals with respect to size, services, and equipment, as well as differences according to specialization for practitioners.[6] Finally, a few courts have revived a theory imposing liability for the absence of technical precautions deemed reasonably prudent, regardless of the prevailing custom among similar professionals or institutions.[7]

Application of the various forms of the locality rule to medical situations where computers were not used and would have made a difference will result in the judicial imposition of different sets

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of responsibilities on different kinds of hospitals and physician specializations. For example, where computer use becomes prevalent among large well-equipped hospitals, a national standard probably would not require that small hospitals with limited resources also use computers. Furthermore, where the use of computers for particular medical conditions becomes standard among doctors who practice at large hospitals located in urban areas, other physicians with access to those hospitals will probably be expected to use those facilities when appropriate.

Medical Computers and Reasonable Prudence

Several courts have recently demonstrated a willingness to discard custom as the only means of determining medical negligence. These decisions have substituted the concept of the reasonably prudent provider, a rule similar to those used in ordinary negligence law, for that of the custom of the provider in good standing as the measure of the requisite standard of care. These decisions could portend a trend which will alter substantially the application of negligence law to providers for the absence of computers in medicine. The remainder of this memorandum considers the creation and application of this doctrine in detail.

The concept of reasonable prudence was first expounded by Judge Learned Hand in 1932 in the case of The T.J. Hooper.[8] The Hooper doctrine was applied to a situation where the owner of two tugboats was held negligent in the sinking of barges under tow because of his failure to equip the tugs with radio receivers. The court reasoned that the captain would have heard broadcast weather reports concerning an approaching storm and, like any prudent sailor, he would have put into a safe port. The storm and destruction of the barges occurred in 1928, at a time when few tugboat companies provided radio transmitters or receivers for their boats. Although the court found that there was no custom at all regarding the use of radios, it concluded that even where the custom was not to provide radios, that custom would not have relieved the tugboat owner of liability because entire professions may ignore or too slowly adopt newly available safety devices. Thus Hooper established the proposition that courts will impose liability for failure to take precautions even where such precautionary techniques may be customarily ignored.

The leading case for imposition of this standard on hospitals is Darling v Charleston Community Memorial Hospital,[9] where the hospital and the attending physician were sued for allegedly negligent treatment which resulted in the amputation of the patient's leg. The Illinois Supreme Court held the hospital liable for failure to require consultation and for providing inadequate care. The court specifically held that two sets of guidelines--the standards of national medical associations and the hospital's own bylaws--now serve such the same function as did evidence of custom. In going beyond this rejection of the locality rule, the court applied the standard of care formula used in ordinary negligence law. In doing so, the court referred to the Hooper premise that even universal disregard of necessary safety measures won't allow an industry to avoid liability for their omission.

The development of this ordinary negligence approach clearly increases the likelihood that doctors and hospitals might be held liable for their failure to use or purchase computers. A court applying the Darling standard could find that failure to use computers for a particular purpose exposed the patient to an inexcusable risk of harm, even where such use was uncommon.

In Nelling v Carey,[10] ophthalmologists were held to be negligent as a matter of law in failing to administer a glaucoma test to a patient for whom such tests were not customary. During the trial the testimony of medical experts for both the patient and the defendants established that the standards of the profession for that speciality in the same or similar circumstances did not require routine pressure tests for glaucoma upon patients under forty years of age. The patient, who was thirty-two years old when the glaucoma was finally diagnosed, had received care from the defendants for more than five years. The court cited language from Hooper in finding that reasonable prudence required the timely application of the pressure test.

The court buttressed its opinion by noting that the test is relatively inexpensive, easy to administer, accurate in detecting the disease, and is otherwise harmless where the physical condition of the eye permits its application, and further explained that the "grave and devastating" result of glaucoma is more than enough justification for requiring the test regardless of professional custom.[11]

The same court, the Supreme Court of Washington, reemphasized and explained the importance of its ruling in Gates v Jensen[12] and Keogan v Holy Family Hospital.[13] Gates concerned the detection of glaucoma, while Keogan addressed a provider's liability for failure to administer an electrocardiogram test in the context of an apparent cardiac event. Once again, the court focused on the importance of the relatively low cost of the tests and the ease of their administration. The court conceded that such tests need only be used where alternative diagnostic procedures were inconclusive or where some abnormality in the patient's condition gave warning of the existence of some undetected problem. When the condition of the patient does indicate the necessity for further examination, said the court, reasonable prudence requires the application of the tests.[14]

These decisions illustrate the importance of several questions governing imposition of liability for the lack of reasonable prudence. These questions include whether the technology in question is available, what kind of an impact this technology would have on the health of particular patients, and what the technology would cost. Each of the decisions discussed above contained a judicial balancing of availability, impact, and cost, and

thus they provide the basis for a discussion of the relevance of Hooper and its progency to computerized medical technologies.

Availability

Courts have approached the issue of availability as two distinctly difference questions, including the usefulness of the technology and the accessibility of the technology. In an early case concerning the use of radar in aircraft, a court refused to find the aircraft operator negligent because of evidence that radar systems available at the time of the aircraft accident were operationally unsatisfactory.[15] The case illustrates the proposition that courts may decline to consider equipment available where such devices are still in the experimental stage of development. Although computers may be used experimentally for particular purposes by some physicians and hospitals, courts are unlikely to impose use on other providers until a system has proven itself capable of fulfilling the particular task for which it was designed.

The separate issue of accessibility focuses on the availability of the equipment to a particular user. Thus, for example, where a doctor may not own a computer, but nevertheless has access to one in a hospital or medical center, that physician will under proper conditions have an affirmative duty to use the available equipment. Under the traditional theory of malpractice, a physician may be held negligent for any failure to use equipment available to him in his own locality if other physicians in good standing would have done so. Furthermore, where particular jurisdictions have expanded the definition of "same locality" to include institutions containing superior medical facilities, physicians could be required to seek computer services for their patients, even though this may require transfer of the patient.

Certificate of need legislation is of critical importance in determining a provider's access to computer technology.[15a] The program is designed to review and determine the need for major capital investment in medical equipment. State regulations indicate what factors will be used to determine need. A hospital must receive a certificate of approval before it can make the desired expenditure. However, that legislation does not articulate a particular standard of conduct in terms of patient care, although the ability of a provider to obtain equipment or provide services clearly has an impact on that standard of care which will be provided by the institution. Thus, where a hospital seeks to obtain a computerized diagnostic device, and its absence for a certificate of need if denied, subsequent patient litigation over injuries allegedly sustained because of the absence of that equipment may well fail. It is quite likely that courts will examine a state's decision concerning the certificate of need in a context similar to any other specific provisions of a regulation actually articulating a standard of conduct. This approach would typically find the hospital to be in compliance with that standard. However, the possibility of a requirement for patient transfer remains where the state's reasoning behind the CON denial includes the existence of an adequate supply of this equipment within the hospital's service area, a justification that is frequently applied.[16]

Reduction of Risk to Patient

Courts may recognize liability as a matter of law for failure to use a computer where application of that equipment in all likelihood would have reduced the risk of ill health for the patient, even though the certainty of an improvement in care is not present. Three examples of the kinds of applications which might improve patient care include the use of computers in diagnosis, selection of therapy, and delivery of therapy.

Diagnosis is perhaps the most important application vulnerable to rule of reasonable prudence. Early, accurate diagnoses improve patient outcomes dramatically, and computer systems already serve physicians in making diagnoses through provision of information and memory enhancement. If a physician does not ask about an issue crucial to a correct diagnosis, and a computer system available to the physician would have asked the question, the computer's use clearly would have increased the likelihood of a correct diagnosis. Under such circumstances, a physician would be liable for failure to apply the computer's expertise. One major limitation on application of the Hooper doctrine in diagnostic situations concerns the extent to which physicians can or should be expected to use computers even though the providers should have detected the problem in their exercise of ordinary care and skill. This situation has led one author to conclude that where common illnesses are concerned, incorrect diagnoses would be the result of the physician's personal error, rather than of any failure to use a computer.[17]

Computers can of course perform tasks which physicians cannot perform alone. Interpretation of electrocardiograms, generation of computed tomographic scans, and measurment of a variety of laboratory tests are all directly possible because of the advances in computers. A judicial finding of negligence as a matter of law seems very likely where computers can diagnose and the physician cannot, given the analogy to the holding in Helling v Carey. Thus where computer performance of diagnostic tasks is superior to that of the physician, a finding of negligence for failure to use is especially likely where the particular computer-assisted task would have affected patient outcome.

Selection of the proper form of treatment also involves a physician's judgment and memory, and the role of computers seems similar to that in diagnoses in that computer applications can master the flood of information about new chemical therapies, including both the suggestion for use of newly available drugs and warnings about the potential for negative interactions among different drugs. The main limitation in this kind of application is ascertaining the physician's state of mind when prescribing the treatment. Where the physician knew about a particular therapy, but rejected its use, courts are unlikely to impose liability for

failure to use a computer which would have reminded the physician of the existence of the therapy. On the other hand, if the physician did not know of the particular form of treatment, but would have been reminded of its existence through use of the computer, courts will be more willing to impose liability for failure to use the computer. The better course for the physician is to document his state of mind in the appropriate medical records.

Computers also serve directly to regulate the delivery of a growing number of medical procedures. For example, computers which monitor or stabilize patients during or following surgery are frequently used in hospitals to protect patients at risk. It seems likely that physicians who have access to such systems will be expected to use them where their application will improve the likelihood of patient survival significantly. Where the cost of these devices is not prohibitive, courts may require providers to purchase such equipment in order to meet the required duty of care.[18]

Cost

Cost of equipment is the last major factor considered by the courts. While the present cost of computers is still relatively high, the declining cost of computer hardware and the availability of an increasing variety of software packages promise to lower the cost of more and more computer applications in the future. The courts will in all likelihood continue to engage in a balancing of interest. Although only a few courts have evinced a willingness to impose a higher standard of care on hospitals than on physicians, there may be judicial justification for imposing strict liability for a hospital's use of equipment while imposing a lesser burden on physicians.[19] This distinction seems appropriate given the growing acceptance of the perspective that a hospital's primary function is to provide services and equipment, while physicians are expected to provide professional skills.[20] In particular, courts could expand the standard of care concerning a hospital's failure to provide certain kinds of facilities where the institution was otherwise capable of acquiring that equipment.

Courts will also examine the broader impact of imposition of requirements for equipment. Courts may find, for example, that while requiring computers for diagnostic purposes in hospitals may reduce risk of injury, the benefits probably would be offset by the increased hospital costs which would accompany use. In the alternative, courts could pursue a regional perspective in finding hospital liability where the institution, itself without computerized diagnostic of therapeutic technologies, failed to transfer the patient to a hospital possessing the necessary equipment.[21]

Conclusion

The erosion of the traditional rule governing the standard of care required of providers has increased the likelihood that courts will find liability where providers fail to make use of computers in medicine, given that such use would have reduced the risk to a patient's health. Although the continued viability of the locality rule in some jurisdictions will preclude recognition of such a duty in those states, the modern trend to redefine the spatial meaning of the locality rule promises the imposition of a use requirement for some kinds of providers.

The application of the rule of reasonable prudence in medicine is of special interest because that rule explicitly relegates custom to a lesser role as one of several factors used to determine medical negligence.

The key question in the application of the Hooper rule to medical computers is whether a judicially-mandated change in medical custom is desirable as determined by a balancing of the expenditures and the health benefits of the acquisition and use of the computers. Medical computers are of course in a state of developmental flux, and while their use can reduce the risk of injury, the precise amount of risk reduction varies with the character of the equipment, its instructions, and its users. Hospitals and physicians inhabit a zone of transition from purely experimental computer use to regular diagnostic and therapeutic application. As the transition occurs, some courts and counsel will probably attempt to apply the lessons of Hooper and its progeny: these application may become a legal trend where societal and institutional costs are low and patient risks can be reduced significantly.

Notes

1. Petros and Scarpelli, Computers, Medical Malpractice, and the Ghost of the T.J. Hooper 5 Rutgers J. of Computers and the Law 15 (1975)

2. See Pearson, Role of Custom in Medical Malpractice Cases 51 Ind. L. J. 528 (1976)

3. See generally Annot., 99 A.L.R.3d 1133 (1980)

4. Dornette, The Legal Impact of Voluntary Standards in Civil Actions Against the Health Care Provider 22 N.Y.L.S. L. Rev. 925, 937 n. 56 (1977)

5. Pederson v. Dumouchel 72 Wash.2d 73, 431 P.2d 973 (1967)

6. Dickinson v Mailliard 175 N.W.2d 588 (Iowa 1970)

7. See notes 10-14 and accompanying text infra.

8. 60 F.2d 737 (2d Cir. 1932); cert. denied 287 U.S. 662 (1933)

9. 50 Ill.App.2d 253, 200 N.E.2d 149 (1964); affirmed 33 Ill.2d 326, 211 N.E.2d 253 (1965); cert. denied 383 U.S. 946 (1966)

10. 83 Wash.2d 514, 519 P.2d 981 (1974)

11. Helling, supra n. 10 at 983

12. 92 Wash.2d 246, 593 P.2d 919 (1979)

13. 95 Wash.2d 306, 622 P.2d 1246 (1980)

14. However, the court in Keogan suggested in dicta that the test was medically indicated under existing custom. See also Darling supra n. 9

15. 224 F.2d 120 (6th Cir. 1955); cert. denied 350 U.S. 937 (1956)

15a. Certificate of need legislation has been promoted by the federal government through the National Health Planning and Resource Development Act of 1974, as amended: Pub. L. No. 95-83, 91 Stat. 383 (1977) (Codified at 42 U.S.C. §§300k-300v (1979))

16. See, e.g., Irvington General Hospital v Dept. of Health of the State of N.J. 149 N.J. Super. 461, 374 A.2d 49 (1977) (Factors include alternative availability of facilities, need for special equipment, impact on service, adequacy of financial resources, and sufficiency of manpower.)

17. Freed, Legal Aspects of Computer Use in Medicine 32 Law & Contemporary Prob. 647, 682 (1967)

18 This is particularly true where the cost of the equipment in question is below the minimum cost review provisions of a state's Certificate of Need law, an amount typically $150,000.

19. Kupusichinsky v U.S. 248 F.Supp. 732 (D.S.C. 1966)

20. Cf. Utter, J., Helling supra n. 10 at 984 (concurring opinion) (strict liability a better theory than reasonable prudence)

21. See, e.g., Blake v District of Columbia Gen. Hosp. (Sup. Ct. July 1981) (liability for failure to transfer to another facility which possessed a CT scanner) (rept. in 9 Health Lawyers News Report No. 8 (August 1981)

Mr. PACKARD. Has a medical school or a training hospital ever been included, to your knowledge, in a lawsuit against a provider, a physician, or some other health provider, on the basis that they did not provide them or teach them adequately or provide them enough information to adequately make their decisions?

Professor BRANNIGAN. In terms of computerized information or other information? Just other information?

Mr. PACKARD. Information that a physician, in developing his treatment plan, did not—was not taught adequately, given enough information. Have the teaching institutions ever been included in such?

Professor BRANNIGAN. Not at what we'll call the pure background level. You can't sue a medical school for producing a lousy physician, using that very broadly. This is one of the distinctions that I was trying to focus on.

If you talk about the failure to get a chart up to a patient's room—that's why information has these multiple meanings—then the answer would be "Yes," and there's a whole series of cases that are cutting this very fine line that involved airline charts, and I cite one of the earliest cases in my article, but there have been cases since then where airline chart manufacturers have been included as defendants in strict liability actions against negligent pilots for giving them the information in an inappropriate way. That's the cutting edge of this field.

Mr. PACKARD. Do you accept the concept that this kind of a system would simply be an adjunct to providing information to a physician, a textbook, a computerized textbook?

Professor BRANNIGAN. No. I accept that when it fills that function, liability is determined one way, but certainly there are other systems that operate directly on the patients or operate in such a way that it's not just a textbook, it's closer to the thermometer readout, and accepting Clem's thing that if he's standing there he'll check the patient, but if he gets it over the telephone he might not, and so therefore I think that's the critical point.

Mr. PACKARD. If it's considered to be used as a textbook, as just an information gathering device, then would it be treated, as far as liability is concerned, on the same basis as an institution that's not liable for producing lousy physicians?

Professor BRANNIGAN. I believe it would fall under—in other words, the institutional liability has been diffused for other reasons unrelated to the concept of the product. There isn't any thing there. I think that in this case it would meet the product-oriented standards that's there some item that we can fix on, but I think the liability would still be negligence. In other words, there would be liability but it would be on a negligence rather than a strict standard. This is not a very certain area, though.

Mr. VOLKMER. Would the gentleman yield on that?

Mr. PACKARD. I'd be pleased to yield.

Mr. VOLKMER. As long as we have no standards, and we have no standards as far as the expert type of computer operations, and there being no standards, and it's just informational systems, and it goes to the doctor, then we're still looking at negligence, are we not?

Professor BRANNIGAN. I believe that that's correct. As long as its filtered through the doctor, we're looking at negligence.

Mr. VOLKMER. So you're still looking at negligence. So it really doesn't make any difference as far as the liability is concerned whether that expert system is any good or not. It may be you have no database and not be worth a darn. If the doctor is still intervening and the liability is on the doctor maybe for negligence, and he discards that and goes ahead and does what he thinks is right, you still have the——

Professor BRANNIGAN. Well, no. I wouldn't say that there's no consequence. In other words, doctors who are routinely liable for negligence are certainly making a lot of noise about malpractice. You have to get into strict liability to impose a lot of liability on them.

So there's no question that the plaintiff's attorney would be coming after on a negligence basis the negligent provision of this particular service to the doctor, and I believe it would be on a negligence basis, but they would certainly go after it, so that we provide a separate pool of liability.

The expanding liability of hospitals for provision of tools to doctors and whether that should be in strict liability or negligence, this is one of the most rapidly expanding areas of medical liability rather than using the term "malpractice" in the United States today.

When I researched it first in 1980, there were only two cases; now I can find hundreds. So the provision—the negligent provision of tools by the hospital for the physician to work with—I mean this is the nature of that type of case.

Mr. VOLKMER. Yes.

I yield back.

Mr. PACKARD. Thank you, Mr. Chairman.

Again, Professor, does the development of new and sophisticated devices used in the medical field tend to increase liability, or does it tend to decrease liability, increasing by virtue of higher expectations, greater exposure, and more technology and training in use of these new and sophisticated devices, fewer perhaps on the basis that it helps them to make fewer mistakes and less malpractice?

Professor BRANNIGAN. My gut prediction is that the vast bulk of malpractice, in my limited experience—and I'm an academic; I don't do much practice; I read it; I don't do it very much—is that an incredible number of cases are simply routine errors, fairly routine errors: Instead of drug A, they gave the patient drug B. It's this kind of mistake that hospitals are routinely sued for; they dropped the patient off the table. It's not at the highest level of medical decisionmaking.

Insofar as these systems routinize and check on these basic fundamental mistakes that occur in complex organizations, I think they will tend to reduce liability. Insofar as we're dealing with the cutting edge of decisionmaking, I think they'll probably have little effect on it until they become used routinely. That would be my gut feeling, that they would reduce it. And they'll reduce not just liability.

This is where, as a consumer-oriented person—reduce injuries; that's the critical thing. It's not so much the question of whether

you get sued after the fact; it's, did the patient get hurt? I think it will actually contribute to better medical care for the patients. We can reduce liability with a law that says the patient can't sue, but the trick is to reduce injuries.

Mr. PACKARD. In your testimony, I gather that you felt that this was not, at least at the current time, a place for FDA to regulate.

Professor BRANNIGAN. I draw sort of a slightly middle ground, which is, they shouldn't regulate it under the device amendments. I believe very strongly that we should have some sort of registration system of all such systems in use so that at least we can pass information back and forth.

If I can use that to expand one point, one of the things that is very disturbing—and I've only begun research in this area—is FDA is perfectly happy to work with secrecy, and they have all kinds of trade secret requirements, and a lot of computer software in the business end is done under trade secrecy.

I think that violates some fundamental idea of peer reviewing and analysis of these types of systems, and one of the things that I would want to make sure is that in any regulation of these systems that secrecy was not only not encouraged or supported by the regulatory authorities, that it was absolutely prohibited by the regulatory authorities.

If anything bothers me at all, it's an expert system where someone can keep as a trade secret how they make the decision in the system, and this is something that FDA is completely geared up to do, and it just also illustrates, it's not like the kinds of things that they worked with in the past, and we may need other forms of protection as have come up in other areas for the intellectual effort involved in these systems, but certainly the kind of secrecy that FDA is willing to do in some of these areas is incompatible with the type of peer review that these systems need. So I would register the systems; I would not further regulate them.

Mr. PACKARD. In answer to a question by the first panel, do you feel that the AMA or other professional societies adequately can monitor and police the system if, in fact, under your recommendation, the FDA would simply be the certifying agent?

Professor BRANNIGAN. Well, again, certifying has a direct implication. I would simply have it the repository of places where these things are.

I think that what Dr. McDonald was describing as the inherent conservatism of the whole system would be adequate, combined with liability, to safeguard patients for a substantial period of time into the future.

I'm not saying that this would last forever, but I certainly think we're at the level of—we're taking two people up in the biplane, we're not building 747's yet, and you can see what's wrong with it, and it's not worth stifling the development to try to make the system perfect.

Mr. PACKARD. One last question, I think, Mr. Chairman, is all I have.

What effect, if any, Professor, will tort reform, as we are seeing it in its preliminary forms, have on the liability question as it relates to the issues that we're discussing this morning?

Unquestionably, tort reform has reached a very high profile as an issue. We're seeing States like my own in California which have initiatives on the ballot where the people are deciding what level of tort they're willing to accept, and we're seeing other States do the same.

Obviously, we're dealing with it here in Washington when we deal with Superfund issues and many, many other issues relating to liability insurance, product liability in the medical area; all these are very, very difficult and problematic areas now that something will be done, in terms of tort reform, in my judgment, in this country.

As we see it in its preliminary form, what effect will this have on this whole question of liability?

Professor BRANNIGAN. Without going into all of the overall policy issues, I think the effect will be fairly small. In other words, it's in the nature of this kind of device that it probably injures people one at a time, if at all, and a lot of tort reform is directed toward other kinds of entities, and probably if it injures people, it injures them fairly quickly.

A lot of the tort reform is oriented toward the mass tort issues, and the long-tailed problems, and a lot of the other issues that have arisen. However, on the good side, one of the real negatives of tort reform is, it requires much more substantial regulation, and this is something the industry now recognizes, that if you don't use the tort system to control defective products, you have to do it directly.

So I have, in other contracts having nothing to do with this, advised people to essentially embrace strict liability in order to avoid inappropriate regulation.

So in that narrow sense, tort reform may force us to come back here and say that the FDA has to much more aggressively regulate these products because all of a sudden you lose the incentives, under certain circumstances. However, that's a broad criticism of some of the proposals.

In terms of these systems, I don't see the effect, and one of the other things is, on the difference between negligence and strict liability, on something like a drug-drug interaction program, as I think I mentioned at quite some length in my article, the difference is very small, because we're talking about really the design stage, and everyone who does liability knows that negligent design and strict liability design defects, these are very small differences. These are made things, not natural artifacts. So I think the liability effect would be very small.

Mr. PACKARD. Thank you, Mr. Chairman, and thanks to the panel.

Mr. VOLKMER. I have one last question, Mr. Belair.

Do you anticipate, if we see an ongoing use of computerization and informational systems, et cetera, in the medical field, further deterioration of the privacy rights of patients? I believe that's so we could possibly anticipate—to go back to the previous question about tort liability—the effect of tort reform on that possibility of more proliferation of Privacy Act suits against persons for, "I lost my job," or whatever have you.

Mr. BELAIR. One of the problems we have right now in enforcing privacy laws, Mr. Chairman, is that most of them don't lend themselves to private rights of action. Either there is no private right of action, or, if there is, it requires the showing of actual damages, which is sometimes hard, especially when the invasion of privacy results in stigma, and emotional distress, and so forth, and of course it's a rare individual who can finance a lawsuit these days, thanks to the fees that lawyers charge; it's an expensive undertaking.

I must see 5 people a month who come to me, and maybe 1 of them has what I would consider a legitimate claim, but only 1 in a 100 can finance litigation.

Mr. VOLKMER. When you say a legitimate claim, you're not saying that they really wouldn't have a cause of action; I mean, they hadn't had wrong done to them, but they failed to have a cause of action on which recovery can be obtained—monetary recovery.

Mr. BELAIR. That's right. They have a cause of action, but there's no provision for attorneys' fees, and they can't finance an action, and so therefore they're left to the American Civil Liberties Union [ACLU], or they're left to——

Mr. VOLKMER. Or if it's merely depression that's resulted from it, because they're now ostracized in their neighborhood or their hometown, or something, that's not——

Mr. BELAIR. Those are in the four out of the five that don't have a cause of action.

Mr. VOLKMER. Right.

Mr. BELAIR. I guess I don't see computerization affecting the ability, one way or the other, of patients to act as private attorneys general.

I really think if we're serious about regulating and protecting privacy, we have got to have some kind of regulatory presence, and I know all the downsides to that. There are lots of downsides to that, and all of us have reason to worry about that, but if we're serious about protecting privacy, there's no other answer.

Mr. VOLKMER. Professor Brannigan.

Professor BRANNIGAN. I would just mention that the United States is way behind most other countries in legislation in the area of privacy protection. We're almost unique among developed countries in having almost no private rights against private data holders, and if the committee is interested, there's a lot of other material.

I do have a colleague coming over for several weeks in June, Dr. Bernd Beier, who is my coauthor in my work on privacy, and he could certainly supply you with some up-to-date information on at least what's being done in Germany. He's the data protection officer for a very large automobile parts manufacturer, and they work all over the world. They have problems, too, in that system, particularly dealing with network systems and microprocessors.

Mr. VOLKMER. Mr. Packard.

Mr. PACKARD. Before you close the hearing, Mr. Chairman, I had a note as a followup of a question to you, Professor Brannigan.

I think you indicated that these systems would probably not be too much liable as a provider of information to the physicians, that

malpractice would probably still be the primary source of suits. Would, however, a physician tend to look toward suits against the system by not providing them adequate information or something going wrong with the information that they've gotten by which they've made their decision, and then they would countersue?

Professor BRANNIGAN. For contribution or indemnity. I think that certainly the effect by defendants of shifting to the system a portion of their own liability—I won't use the word "responsibility;" I'll use the word "liability"—that will be an aggressive attempt. That has occurred, and that is mostly handled by contractual relationships among the various players in the game, and a lot of hospitals, again, in my small survey, have taken on that liability as a way of attracting the best and most competent physicians, so that the physician gets that as a matter of contract rather than as a matter of tort law. They simply cover them for any of those kinds of errors.

Mr. PACKARD. I see.

Mr. VOLKMER. They're basically indemnified, then.

Professor BRANNIGAN. That's right, because they can acquire insurance at a more efficient rate.

Mr. PACKARD. OK. Thank you.

Mr. VOLKMER. OK. Once again I would like to thank our witnesses, both panels, for appearing here today and sharing with us their opinions on these subjects. This has been a very valuable hearing for the subcommittee.

It definitely appears that the subcommittee needs a better understanding of the Food and Drug Administration activities in this area, and therefore I hope to hold hearings later this year for the purpose of receiving a formal statement from the Director of the Center for Devices and Radiological Health.

I would like to explore further other areas identified in the testimony presented here that deserve greater examination. We also need the views of other affected parties on the topics raised here today. So I welcome the interest displayed here and invite interested parties to contact the subcommittee to discuss this field. I also wish to thank Congressman Packard for his participation here today and look forward to his continued assistance.

With that, the subcommittee will stand adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.]

APPENDIX I

Additional Statements Submitted for the Record

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUITE 2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-6371

4 March 1986

Hon. Frank D. Young, Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner:

The Subcommittee on Investigations and Oversight of the Committee on Science and Technology will hold a hearing on March 18, 1986, on the use of information technology and artificial intelligence techiques in the health care system. The hearing will examine some of the present medical applications of artificial intelligence research and the policy issues involved in the growing use of medical computer systems.

We would appreciate a statement for the record from the Center for Devices and Radiological Health that describes FDA's present position on the need for regulation in this field. This statement should specifically include the following information:

- Under what authority does FDA regulate computer software designed for applications in the health care system?
- Has the agency decided to regulate medical software under this authority?
- What policy exists regarding the regulation of medical software at the present time?
- What policy alternatives are being considered in the development of the agency's policy statement and what steps under the Medical Device Amendments are applicable to the future use of these information systems?

The Subcommittee would also be interested in FDA's oversight efforts involving over-the-counter sales of these systems, including any actions FDA has taken to assure that the public welfare is not compromised.

Hon. Frank D. Young
4 March 1986
Page Two

In preparation for the hearing, the Subcommittee would appreciate receiving copies of reports prepared by your staff in this area. We have a specific interest in the following documents:

- o Report of the Task Force on Software and Computerized Devices (1981 or 1982);
- o Report of the Program Management Committee on Software and Computerized Devices (December 31, 1984);
- o the most recent version of the draft policy statement on software and computerized devices under review at the Center for Devices and Radiological Health, and;
- o Guidelines for Review of Software-Driven Devices.

The written statement may be as detailed as you wish, and will be made a part of the record in its entirety. Please send the statement, before March 14, 1986, to:

James H. Paul
Subcommittee on Investigations
and Oversight
822 House Annex 1
300 New Jersey Ave., SE
Washington, DC 20515

Your cooperation is greatly appreciated.

Sincerely,

Harold L. Volkmer

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 16, 1986

The Honorable Harold L. Volkmer
Chairman, Subcommittee on
Investigations and Oversight
Committee on Science and Technology
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

I am providing you with the following documents on computerized medical devices and software that you requested in your letter to Commissioner Young of March 4, 1986:

- Report of the Task Force on Software and Computerized Devices (January 1982);
- Report of the Program Management Committee on Software and Computerized Devices (December 31, 1984);
- the most recent version of a draft policy statement on software and computerized devices now under review in FDA's Center for Devices and Radiological Health, and;
- Guidelines for Review of Software-Driven Devices (draft dated March 1 1986).

All of these are confidential, internal documents on policy matters that have not been resolved by the Food and Drug Administration and presently reflect solely the views of an Agency task force or individual author. They would be withheld by the Agency if requested under the Freedom of Information Act. We therefore request that the Subcommittee not release or otherwise publicly disclose their contents. I anticipate that the statement for the record that you also requested in your letter of March 4 for your upcoming hearing on April 21 will be transmitted to you in the very near future.

If we can be of any further assistance, please let us know.

Sincerely yours,

Michael A. Eck

for Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT FOR THE RECORD

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEARING BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

APRIL 21, 1986

The Food and Drug Administration (FDA) is pleased to assist the Subcommittee on Investigations and Oversight in addressing our current policy on the application of computer technology to medical devices.

The mission of the FDA is to provide consumer protection through judicious enforcement of the various laws entrusted to it. Our primary responsibility with regard to medical devices is to ensure these products are safe and effective for their intended uses. The regulatory policy of FDA regarding computers and software used in medical devices has been evolving over the last 5 years in response to the development and implementation of computer technology by the medical devices industry. The specifics of FDA's policy are still under development. Meanwhile, we are addressing industry developments on a case-by-case basis while awaiting the emergence of clear patterns in the application of computer technology to medical devices. Because the industry is changing rapidly, it is possible that the policy positions we present in this statement could change significantly as patterns in the industry change. It is with this warning in mind that the FDA responds to the Subcommittee's request for information pertaining to FDA policy on computers in medical devices.

FDA regards some computer hardware and medical software as medical devices, as defined by the Federal Food, Drug and Cosmetic (FDC) Act. Section 201(h) of the Act defines a medical device as an ". . . instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any

component, part, or accessory which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body . . . and which does not achieve any of its principal intended purposes through chemical action . . . which is not . . . metabolized for the achievement of any of its principal intended purposes."

FDA's regulation of computers and software in medicine is not new. FDA has completed premarket approval (PMA) reviews of computer-related products such as cardiac pacemaker programmers, patient monitoring equipment, and magnetic resonance imaging (MRI) machines. Some of these reviews date back to the 1970's. However, in the past few years there has been a rapid increase in the number and variety of such products. Of particular importance to FDA is the increasingly central role computer technology is taking in medical systems. With a judicious selection of computer products, today's health care professional can arrive at or verify a result or diagnosis, determine or even apply a therapeutic regime, and check his cash flow or billing status. It is not inconceivable that in the near future there will be a product which combines all of these capabilities, with decisionmaking provided by the system instead of the health care professional.

This burgeoning growth of computers in medicine and its more pivotal role poses new challenges to FDA, since we must assure adequacy and consistency in the Agency's reviews of new computer software devices before they are marketed. We also need guidance for field personnel who inspect manufacturers of these products. In addition, many

manufacturers of new, computer-related medical technologies are not aware of their responsibilities under the law because they are not part of the traditional medical device industry.

In an effort to reduce the possibility of misunderstanding, FDA, through its Center for Devices and Radiological Health, is developing a detailed policy statement on computer-related devices to reaffirm and clarify existing requirements. Once this policy is finalized, it will be communicated to the current and emerging segments of the medical device industry.

Policy Outline

What follows is a general description of how medical devices are regulated with examples of how computerized devices fit into this framework.

The Medical Device Amendments of 1976 prescribe a tiered system of regulatory controls commensurate with the risks associated with the devices, and the testing needed to ensure the device is effective.

The FDC Act requires FDA to classify devices intended for human use into one of three regulatory classes: Class I (General Controls), Class II (Performance Standards), and Class III (Premarket Approval). The law directs FDA to establish panels of experts, composed of members from the research and medical communities, industry, and consumers, to provide advice and recommendations on device classification. The advisory panels consider:

-- persons for whose use the device is intended;

-- conditions of use for the device;

-- probable benefit to health from use of the device weighed against any probable injury or illness from such use; and

-- the reliability of the device.

After receiving panel recommendations, FDA publishes for public comment, a proposed regulation assigning the device to a class. A final decision is published in the Federal Register after evaluating comments to the proposal.

An explanation of the device classes and examples of how computerized devices fit into these classes follows:

-- Class I devices are those for which general controls such as registration, labeling, and good manufacturing practices are sufficient to assure safety and effectiveness.

An example of a computer-related device proposed for Class I is the calculator/data processing module for clinical use. This is an electronic device used to store, retrieve, and process laboratory data.

To minimize unnecessary regulatory control and resource commitment by manufacturers and FDA, some devices are exempted from certain general controls of Class I. For example, FDA exempts manufacturers of general

purpose articles from the registration and listing requirements. General purpose articles are defined as ". . . chemical reagents or laboratory equipment whose uses are generally known by persons trained in their uses and which are not labeled or promoted for medical uses." FDA will consider the broadest possible interpretation of "general purpose articles" as a first approach to the regulation of computerized devices.

-- Class II devices are those for which general controls are insufficient to assure safety and effectiveness, and existing information is sufficient to establish a performance standard that provides such assurance. This class of devices must comply with general controls and also with mandatory performance standards developed according to provisions in the FDC Act. Development of performance standards may be a lengthy and complicated process, and until standards are established by regulation, only general controls apply to these devices.

An example of a computer-related device proposed for Class II is the programmable diagnostic computer, a device that computes various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices. The definition of this device type includes any associated commercially supplied software.

-- Class III devices are those for which insufficient information exists to assure that general controls and performance standards provide reasonable assurance of safety and effectiveness. Generally, these devices are represented to be life-sustaining or life-supporting, or are implanted in the body, or present potential unreasonable risk of illness or injury.

An example of a computer-related device proposed for Class III is the obstetric data analyzer. This device, used during labor, analyzes data from fetal and maternal monitors to provide clinical diagnosis of fetal well-being. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

Specific Issues

Some specific issues of concern to FDA or issues that have been raised by the Subcommittee include quality assurance data needed for device approval, stand-alone software, over-the-counter (OTC) sales of medical device software, and the limitations imposed by Agency resources.

Quality Assurance of Computerized Devices

The reliability of software systems and higher order integrated circuits are extremely difficult to assess because of their complexity. In general it is impractical to test them for every possible input value, timing condition, environmental condition, logic error, coding error and other opportunity for failure. The best that can be achieved is a finding that the state-of-the-art in testing such devices has been applied and acceptable results obtained. Manufacturing and quality

assurance programs for medical devices employing software and integrated circuits should maintain adequate documentation of test efforts.

Some of the quality assurance elements which FDA will need to consider in approving a computer-related medical device are:

-- appropriateness of model or algorithm;
-- completeness of model or algorithm;
-- protection against inadvertent changes in programs (model or algorithm);
-- software safety (protection against unsafe errors of execution)
-- adequacy of labeling for performance specifications, operating environment, interfaces; and
-- software maintenance (proper development, integration and testing of revisions to the model or algorithm).

Stand-alone Software

No separate policy for computer software presently exists nor is one envisioned for the future. Medical software products that are marketed separately from a computer (generally referred to as stand-alone software) and used with a computer to form a system which operates as a medical device will be treated as a medical device.

Computer software that meets the definition of a medical device will be regulated commensurate with the product's intended use and its inherent public health risks.

As mentioned above, FDA is already conducting premarketing reviews of new medical devices that feature computers as an integral part of their operation. Any issues which the software presents are addressed in the review of the system in which it is used. The regulatory requirements applied to these devices result from their medical function, not the existence of the computer. Based on existing authority, FDA has also initiated post-marketing actions against these products when they have been found to be defective.

Over-the-Counter Sales

Over-the-counter sales of computer-related medical devices are regulated through the labeling provisions of the law. The prescription or OTC status of medical devices is determined by judging whether adequate directions for use by consumers can be written to ensure the safe use of computer-related devices. If such instructions cannot be developed, these products will be treated as prescription devices.

Resources

Agency resources are another important consideration. FDA is already facing an increasing workload in the medical device area. Today's high technology revolution has spawned ever more complex and sophisticated products for our review, some with computers and some without. We must set priorities based upon potential risks to patients and not just the presence of a computer. We believe that in a time of increasing demands and limited resources, our policy guidance in this area must enable the Agency to concentrate on critical issues based on potential risks and permit devices, including software which pose comparatively lower risk, to be marketed with limited regulations.

Summary

In summation, FDA is in the process of developing an overall policy for computer technology used in medical devices. It can be expected that the policy will apply equally to computer hardware and software; it may provide for "exemptions" from certain regulations when no specific and only general medical claims are made, and it will call for the minimum level of regulatory control necessary to ensure safety and effectiveness. Finally, available resources suggest a policy that concentrates on critical devices and limits regulation of lower risk devices.

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Republican Staff Director

4 March 1986

Mr. Larry DeNardis
Assistant Secretary for Legislation
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20205

Dear Mr. Secretary:

The Subcommittee on Investigations and Oversight of the Committee on Science and Technology will hold a hearing on March 18, 1986, on the use of information technology and artificial intelligence techiques in the health care system. The hearing will examine some of the present medical applications of artificial intelligence research and the policy issues involved in the growing use of medical computer systems.

Because the National Institutes of Health (NIH) have a significant role in supporting this area of research, I would like to have a statement for the record about your agency's present work in the areas of computerized medical records and in the development of medical expert systems.

The Subcommittee is especially interested in the present level of Federal support for applying artificial intelligence techniques in the health care system, and a description of the projects now funded by your Institute. We would also appreciate discussion of the goals NIH is pursuing by funding these research projects, any recommendations you might wish to make regarding further support needed in this area, and the future direction NIH intends to take in this field. We would appreciate a similar discussion of support extended by NIH for the development of computerized storage systems for medical records.

Mr. Larry DeNardis
4 March 1986
Page Two

This written statement may be as detailed as you wish, and will be made a part of the record in its entirety. Please send this statement, before March 14, 1986, to:

James H. Paul
Subcommittee on Investigations
and Oversight
822 House Annex 1
300 New Jersey Ave., SE
Washington, DC 20515

Your cooperation is greatly appreciated.

Sincerely,

Harold L. Volkmer

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

The Honorable Harold L. Volkmer
Chairman
Science and Technology Subcommittee
on Investigations and Oversight
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your request, enclosed is a statement for the record regarding National Institutes of Health efforts in the area of artificial intelligence research for the Subcommittee's April 21 hearing on the use of information technology and artificial intelligence techniques in the health care system.

If we can be of further assistance, please let me know.

Sincerely yours,

Lawrence J. DeNardis
Acting Assistant Secretary
for Legislation

Enclosure

STATEMENT FOR THE RECORD

DONALD A.B. LINDBERG, M.D.
DIRECTOR, NATIONAL LIBRARY OF MEDICINE

and

SUZANNE S. STIMLER, PH.D.
DIRECTOR, BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM
DIVISION OF RESEARCH RESOURCES

NATIONAL INSTITUTES OF HEALTH

for the APRIL 21, 1986, HEARING ON
INFORMATION TECHNOLOGIES IN THE HEALTH CARE SYSTEMS

HOUSE SCIENCE AND TECHNOLOGY COMMITTEE
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

At the National Institutes of Health (NIH), the responsibility for training and research support for artificial intelligence and expert systems lies primarily with the National Library of Medicine (NLM) and the Division of Research Resources (DRR).

Artificial intelligence is a branch of computer science which deals with decision processes, particularly in the context of drawing conclusions or solving problems on the basis of logical inference and a knowledge base. Since the early 1970's, the principles of artificial intelligence have found increasing application in the development of "expert systems," in which the computer is provided detailed information in well defined areas and used to assist health professionals in analyzing actual problems. Today, these two fields--artificial intelligence and expert systems--are the most rapidly growing areas in what has now come to be called "Medical Informatics."

PROGRAMS OF THE DIVISION OF RESEARCH RESOURCES

Background of DRR Research Support

The Biomedical Research Technology Program of the Division of Research Resources has been supporting research on applications of artificial intelligence in medicine and biomedical science for more than 20 years. The focus of this support has been a computer linked community for artificial intelligence research and applications projects with special emphasis in biological and medical areas. Centers on the east and west coasts provide both computer support and methodological support to scientists throughout the nation.

The center at Stanford University was responsible for some of the first specific applications of artificial intelligence technology to biomedical areas through development of systems such as DENDRAL (chemical structure elucidation), MYCIN (infectious disease diagnosis and therapy) and INTERNIST (differential disease diagnosis). The rule based logic system built into the MYCIN program was subsequently developed as a general decision framework program which could be applied to many applications problems, and became the initial basis for "expert systems." Thus, the effects of the direct and collaborative support of research projects in artificial intellignce in medicine at these centers have extended far beyond the host institutions. In fiscal year 1985, the DRR program spent $3.2 million in this area supporting both research centers and individual applications projects.

Current Status of DRR Programs

Among the projects funded by the Division of Research Resources:

1. A collaborative effort between Rutgers, the University of California and the IBM Corporation to develop a hand-held computer to assist primary health care workers in developing countries in the management of common, potentially blinding eye disorders. In developing countries, blindness is a major health problem whose control depends on the application of simple measures by frontline workers. Advances in portable computer technology have made feasible a self-contained package incorporating a set of guidelines for diagnosis and treatment to be used in the field. The Agency for International Development is also supporting parts of this activity.

2. A cost effective, workstation-based consultation system, ONCOCIN, for the management of cancer chemotherapy treatment protocols in outpatient cancer clinics is being developed at Stanford University. The initial computer program was designed to aid physicians in the treatment of lymphomas, and has been evaluated in cancer clinics. Current efforts are to modify the protocol management system so that it can be used on small self-contained workstation computers suitable for smaller clinics or even a physician's office. This project has also been supported by the NLM.

3. A broader diagnostic program, INTERNIST-CADUCEUS, supported by both the DRR and NLM at the University of Pittsburgh, addresses diseases of internal medicine. A detailed knowledge base on diseases of internal medicine and the diagnostic criteria for such diseases has been developed. With the aid of a question and answer program, a physician can explore the possible diagnoses for particular patients, and receive suggestions for further tests or examination criteria for particular diseases.

PROGRAMS OF THE NATIONAL LIBRARY OF MEDICINE

Background of NLM Research and Training Support

In 1971, a committee of nonfederal experts chaired by Dr. Eugene Stead of Duke University urged that the National Library of Medicine begin a program of training grants for the medical computer sciences. The grants would be funded under the Medical Library Assistance Act of 1965.

The NLM Board of Regents concurred in this recommendation and, in 1972, the first training program grants were awarded. At its zenith, 10 programs were simultaneously active. They were quite diverse, ranging from computer orientation to advanced research career training. The goal was to convey advanced computer skills to medical school faculty who, by using these skills in their research and teaching activities would serve as role models for students. This goal was attained, although it must be admitted that many investigators and clinicians were independently becoming "computer literate."

In 1978, a nonfederal task force studied the Library's research grants program and recommended a concentration on computer science research in the management of knowledge. Again, the Library's Board of Regents concurred, and a new program called "Computers in Medicine" was announced in 1979. Under it, there were five major 5-year awards to prominent universities as well as small projects for new investigators and research career awards. Although the new program was well received--even obtaining Congressional recognition in the FY 1980 appropriation--it was not possible to fund more of the major awards. Support for smaller investigator-initiated projects and for younger investigators continued, however.

Even with relatively limited fiscal resources, the program attracted promising young investigators and became identified as the program of choice for research into medical knowledge issues, not restricted to certain categorical diseases. In 1982, a study of program accomplishments showed that awardees were publishing their results at an impressive rate, in both medical and general scientific journals. In 1983, the designation Computers in Medicine was changed to Medical Informatics. The importance of this field was recognized once again in the NLM appropriation for FY 1985. A budget increase that year made it possible to attract and fund a significant number of new applications.

In addition to grant-supported activities, intramural research and development into improved information systems is conducted by the Lister Hill National Center for Biomedical Communications, the research and development component of the National Library of Medicine. In its projects, the Center has used a wide variety of technologies--computer, microwave, satellite, cable television, videodisc, and so forth--and has placed much emphasis on investigating artificial-intelligence-based expert systems and (more generally) knowledge-based systems to support clinical decision making.

Background of NLM's Program Interest

NLM's fundamental job is to organize, store, and provide access to the biomedical literature. Over its 150-year history, NLM has changed its methods to employ the latest in information management technology. Currently, computers are used to store and access medical knowledge as (largely) textual representations of scientific literature. There are already significant exceptions, however. The various toxicology data bases are factual and numeric as contrasted with those that are preponderantly bibliographical and textual.

Even better representations of medical knowledge are needed and seem to be possible. The artificial intelligence techniques offer our brightest hope for optimal information service by NLM in support of medical decision-making by American health professionals in the future. Consequently, NLM has consistently and enthusiastically supported the development of this field and the testing of the increasingly practical products of its research.

The goals NLM has for the field include:

1. improved representation of medical knowledge and judgment,

2. automatic indexing and cataloging systems for processing the scientific literature,

3. intelligent assistance to users in framing searches of our data bases and intelligent assistance to them in evaluating the results of their retrievals,

4. contributions to the development of a Unified Medical Language System to facilitate sharing of knowledge between clinical medicine, research and education,

5. improved patient care through computer enhancement of clinical decision making, and

6. improved health sciences education through expert systems in personal information management and lifetime learning.

Current Status of NLM Intramural Programs

Within the National Library of Medicine itself, significant Medical Informatics work involving expert systems includes:

1. An expert system known as AI/RHEUM, based in artificial intelligence principles, has been devised for rheumatology. It consists of two major components: a diagnostic consultant system and a patient management consultant system for cases of rheumatoid

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arthritis. In its current state, the AI/RHEUM diagnostic consultant "knows" of 26 rheumatologic diseases, reasons from a patient data checklist of 879 elements, and has been tested with more than 500 documented clinical cases. The management model is being tested with a small set of cases and will be further refined this year.

2. An expert system, known as AI/COAG, has been developed to assist practitioners with the diagnosis and management of problems in hemostasis. This is a medical specialty where acknowledged experts are very limited in number and often poorly distributed geographically. AI/COAG uses branching logic and a menu-selection approach to allow quick progression through the parts of the patient's history which are unremarkable and drops to deeper levels of questioning to elicit increasingly detailed answers when specific items denoting a positive bleeding history are identified. The initial system has been tested and is now being expanded and refined.

3. NLM, working with other government agencies, is building an expert system to facilitate retrieving information to respond to chemical emergencies. The expert system will provide artificial intelligence based assistance to the person who is coordinating the response at the scene of the emergency. The system will "ask questions" to discover the true nature of the emergency, search its memory for precedent situations, then to remote data bases to retrieve pertinent information to be used by the on-scene response team.

4. Finally, NLM staff have developed an online indexing system that is speeding up the indexing process at the Library. This has been of immense help, since NLM indexes some 300,000 journal articles each year for its data bases. Similar techniques are being applied to the process of cataloging books.

Current Status of NLM Extramural Programs

By the end of 1985, NLM was supporting 23 active research grants, six new investigators, and six research career development awards. The total amount was $4,297,000. The five major training programs were able to appoint 28 postdoctoral trainees, at a total of $1,091,000. During the period 1980-1985, NLM supported 165 trainees, 51 investigator-initiated research projects, 20 new investigator awards, and four program projects.

Among the projects funded by the National Library of Medicine:

1. A collaborative effort between Tufts and MIT to investigate expert systems with computed medical decision analysis, and at Dartmouth, the funding of research involving decision analysis protocols programmed on microcomputers and studied in the context of a medical curriculum. The medical domains include nephrology and laboratory medicine, especially connective tissue disease.

2. At the Brigham and Women's Hospital (Boston), a project in the complex field of radiology called "Investigations in Clinical Decision Making." The diagnostic areas include mammography and coronary arteriography.

3. At the University of Missouri, Columbia, a successful prototypical consultant system for genetic diseases such as deaf-blind syndrome. This is an application of artificial intelligence methodologies to genetic diagnosis.

4. "Feedback Technology to Improve Physician Judgment," at the University of Wisconsin and "Computer-Based Clinical Decision Analysis" at the Deseret Foundation (Salt Lake City) are both intended to assist physician decision making in patient care, including radiologic diagnoses of pulmonary disease.

5. "INTERNIST-CADUCEUS: A Computer-Based Diagnostic Consultant," at the University of Pittsburgh, is an artificial intelligence consultant system covering all of internal medicine (nearly 600 diseases). This is the largest biomedical knowledge base extant, covering an entire medical specialty.

<u>Summary</u>

Medical Informatics, with its emphasis on the use of new computer and communications technology to apply medical knowledge to health care, is a vital link between the laboratory, on the one hand, and the classroom and bedside on the other. Both the National Library and Medicine and the Division of Research Resources are committed to furthering this field with continued extramural support and in-house research. Such support is necessary if we are to realize the maximum return on our substantial investment in biomedical research.

APPENDIX II

Additional Material Submitted for the Record

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUITE 2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-6371

20 May 1986

Dr. Jack Myers
Professor Emeritus
University of Pittsburgh
1291 Scaife Hall
Pittsburgh, Pennsylvania 15261

Dear Dr. Myers:

Enclosed is a copy of the transcript from the April 21, 1986, hearing at which you testified before the Subcommittee on Investigations and Oversight on information technologies in the health care system. Attached to the transcript are instructions for submitting requests for changes or clarifications. Please review these instructions and the enclosed transcript of your remarks carefully. Your copy of the transcript, together with any written requests for changes, should be returned by June 30, 1986, to:

James H. Paul
Subcommittee on Investigations and Oversight
622 House Annex I
Washington, DC 20515-6301

Also, the Subcommittee has developed other questions as a result of the hearing and would appreciate your response to them. Your answers may be submitted at the time your transcript is returned.

1. Why did you elect to use clinical trials as your means of verifying your design?

   a. What alternative methods were available?

   b. Why were these methods rejected?

   c. Is the FDA statement correct when it states that the complexity of software argues against an ability to test all of the pathways possible?

   d. If so, will verification by clinical trials be a sufficient trial of the knowledge base and inference engine?

2. CADUCEUS, as it is presently designed, requires a physician's interpretation. Can instructions be written so that it would be accessible to laymen?

   a. If so, could these systems be safely sold over-the-counter or in computer software stores for use by the public?

Dr. Jack Myers
20 May 1980
Page Two

3. In Medical Education in the Information Age, your committee expressed the view that computers should assume the role of providing necessary medical information to students, relieving them of the need to memorize an overwhelming amount of material. How would this affect the development of medical judgement?

   a. How much does a physician need to know about a disease in order to decide on an appropriate treatment?

4. How do you determine that a disease has been sufficiently characterized, and thus is a candidate for inclusion in the CADUCEUS knowledge base?

   a. Given that medicine is such a dynamic endeavor, how can the CADUCEUS knowledge base be kept current?

5. Enclosed is a copy of a statement submitted for the record by the National Institutes of Health.

   a. Are you satisfied with the current focus of NIH research in the application of artificial intelligence techniques to medicine?

   b. What changes or new areas of emphasis would you recommend?

6. FDA defines a Class 1 medical device as "...laboratory equipment whose uses are generally known by persons trained in this area and which are not labeled or promoted for general uses." Can CADUCEUS meet that standard?

   a. For a Class 2 device, FDA requires the establishment of a performance standard. How would you set such a standard for CADUCEUS?

Your testimony at the hearing was extremely valuable to the Members, and I want to extend our thanks for your participation and service to the Subcommittee.

Sincerely,

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

University of Pittsburgh
SCHOOL OF MEDICINE
University Professor (Medicine) Emeritus

June 5, 1986

Mr. James H. Paul
Subcommittee on Investigations and Oversight
822 House Annex 1
Washington, D.C., 20515-6307

Dear Mr. Paul:

My answers to the various questions which the Subcommittee on Investigations and Oversight put to me in the letter of 20 May 1986 follow. Incidentally I did not receive the letter until 28 May and have been out of town for a good part of the time since.

1. I know of no method to test a computerized diagnostic system like ours except to analyze the performance of the system on large numbers of cases,usually difficult from the diagnostic standpoint. Up to this time, those analyses for all have been exercises to detect omissions, errors, and refinements to be made in the program. As I believe I explained, the program currently is incomplete in that some 150 diseases in internal medicine remain to be programmed, and therefore it has not been placed in actual clinical use.

The FDA statement is correct that "the complexity of software argues against an ability to test all of the pathways possible". However, this point must be evaluated from the standpoints that medicine is not and never will be a perfect science, no medical textbook is perfect, and no physician diagnostician is perfect. The real question is how much such systems as ours aid the physician overall by providing diagnostic consultant advice. If the government and the public require perfect expert diagnostic systems then we shall have to abandon such expert systems development except as toys. Controlled clinical trials should demonstrate whether or not such computerized diagnostic consultant systems contribute to a significant and high level of improvement in medical diagnosis.

2. It has been our strong decision from the beginning that expert systems like INTERNIST-I must be used only by professionals and that the results require a physicians interpretation. We never expect to modify our system for use by laymen.

3. Medical judgement is acquired by the intelligent manipulation of medical information and by observing experts do such. Obviously the more information one has stored in his memory probably the better his judgment will be, but we have all known good memorizers who did not demonstrate commensurately good judgement. A very important point is that it is impossible by many fold for a medical student to

1291 SCAIFE HALL, PITTSBURGH, PA. 15261 • (412) 624-2649

memorize the factual medical information available. What our report was stressing was the point that excessive emphasis in the medical curriculum on memorization be reduced, not abandoned.

The more a physician knows about a disease generally the better is his treatment of it. On the other hand, a good proportion of medical information is not pertinent to treatment.

4. To determine that a disease has been sufficiently characterized to be programmed is a matter of mature judgment, just as is the case for that disease to be included in a medical textbook. It is a large and difficult problem to keep a large knowledge base such as that of INTERNIST-I up-to-date. However, the knowledge base can be kept as current as medical textbooks and probably more so because of the lag time in book publication.

For example, we waited about 18 months for information to accumulate on AIDS as a disease before we decided to program it about a year and a half ago. Additional information has been periodically added since that time.

5. The Division of Research Resources of the NIH and that National Library of Medicine in my opinion have been quite far-sighted and innovative in the support of artificial intelligence in medicine and they remain so. New areas of emphasis will need to be proposed by the academic community, and currently we are in a stage of moderate stagnation.

6. The hardware used by INTERNIST-I can be defined as laboratory equipment and has a high degree of reliability. I would not classify the software as a medical device in the FDA sense; it is really an intellectual device like a textbook or monograph. However, it is anticipated that a controlled field trial of the knowledge base and inference engine should demonstrate and need to demonstrate that the computerized medical consultant program performs as well if not better than the expert human consultant and that the system led to improvement in medical diagnosis. The controlled clinical trials will be held in academic medical centers, first in ours at the University of Pittsburgh and then at others, where medical and diagnostic standards are high.

The only important inaccuracy in the transcript of my testimony is on line 164 where other should read various. My conversational English was not always of high clarity but nothing is really inaccurate.

Sincerely yours,

J. D. Myers, M.D.

JDM/rt

THE UNIVERSITY OF UTAH

DEPARTMENT OF MEDICAL INFORMATICS
LDS HOSPITAL
325 EIGHTH AVENUE
SALT LAKE CITY, UTAH 84143
801-321-1166

July 11, 1986

Harold L. Volkmer
Chairman
Subcommittee on Investigations and Oversights
House of Representatives Committee on
Science and Technology
822 House Annex One
Washington, D.C. 20515-6307

Dear Mr. Volkmer:

I am sorry to be slow in getting my response back to you. Unfortunately the material was sent to my former address in Houston, Texas and it took a month for the post office to forward it to me here in Salt Lake City. The materials were here on my return from a family vacation at the end of June. Thank you for the opportunity of letting me participate in this subcommittee hearing. I have reviewed the transcript and am returning it with a few corrections. In response to your further questions:

1. In a 1982 report, the Committee on Science and Technology noted that one of the greatest barriers to wide-scale use of medical information systems was the reluctance of physicians to take advantage of their capabilities. How did you address this problem at LDS Hospital and with what success?

The HELP System used at LDS Hospital has been under development and in clinical use for well over a decade. Medical data entered into the system comes primarily from the clinical laboratory, nurses, therapists and technicians. Physicians users are primarily recipients of data output from the HELP system with its extensive communications and decision-making capability. Over the years we have developed a "sociological" structure within the hospital which is conducive to physicians to use computer records. Recently we have added a capability of phone-in access from physicians offices which has been a successful venture. In my experience, it is clear that establishing the correct "sociology" where physicians gain a trust in the medical computer system is important. Most hospital computer systems used in the past have been "administrative" or billing systems. The HELP system emphasizes physician oriented "clinical" data collection. The ability of physicians to get results promptly and accurately is very helpful to them and not threatening. Physician appreciate being notified when their patient might receive a contraindicated drug. In this way our system functions as an on-line "safety net".

2. Please describe the negotiations that led to the agreement permitting Control Data Corporation to market the HELP System.

   a. Professor Brannigan's testimony indicates that LDS Hospital could conceivably be held strictly liable for errors in the HELP system. because the hospital developed the underlying software. Was liability a concern to the hospital during these negotiations?

LDS Hospital's primary interest at the time of the contract negotiations was to get financial support for continued computer system development. Control Data saw the advantages of the system and wanted to provide it in the commercial marketplace. The only reluctance Control Data had was that they did not want to get into the marketing of "medical decision-making strategies" which they were concerned might be thought of as practicing medicine. Therefore Control Data left the establishment of the medical knowledge base up to the hospitals where they sold systems, with the suggestion that the hospital contact LDS Hospital for initial concepts. At the start of our negotiations, liability was not a major concern. In more recent times the liability issue has become more of a concern (especially since my attendance at the Congressional Hearings!).

3. During the hearing, you stated that FDA had not communicated with you regarding the development of the HELP system. When Control Data Corporation began marketing the system, was any review required?.

As far as I know, no contact was required for LDS Hospital to sell the computer system to Control Data Corporation. As far as I know, no action by FDA was required of Control Data Corporation in the 1981 contract time frame.

4. Please discuss the legal problems you alluded to in establishing remote access capability for your system.

Remote access to the system was an easy technological task, but required a lengthy legal and patient privacy review before being approved. A multi-step plan was implemented which allows staff physicians to purchase remote access services from the LDS hospital. A copy of the application form required of physician is attached for your interest. Multiple steps are taken to assure the security of the system. These include:

a. A floppy disk, which contains an encrypted log-on security code, is issued to authorized physicians who agree to keep it in a secure place and be responsible for it. The disk is also "copy protected" to prevent easy duplication.

b. Physicians agree to maintain the patient's privacy the same way as having access to the computer and other records when they are on-site at LDS hospital.

c. The physicians agree to notify LDS Hospital if their floppy disk is lost or stolen so that the lost code "authorization" can be removed from the HELP system.

d. A record is made of each call by access code is kept. Record are also kept of which patient's data are reviewed.

e. Physicians agree to hold LDS Hospital harmless if there are any claims arising from the use of their access code.

f. We review the access to the system every month and look for appropriateness of data access and have close communications with the physician users.

5. How is the HELP System used to meet information demands from third-party insurers?

HELP system records are used extensively for providing documentation of care given for third-party insurers. We are able to provide a level of documentation of both clinical and administrative data which minimizes "challenges" to the accuracy of the care given which saves both the hospital and third-party insurers time and effort. For example we have recently started charging patients for nursing care based on the patient's illness acuity. Also contained within the system is a medical records module which includes DRG coding, ICD-9 coding and a discharge summary coding scheme.

6. How has the HELP System been used to meet the demands imposed by Medicare's new prospective payment system?

The System has been a valuable tool in helping the hospital manage its resources and in meeting Medicare prospective payment requirements. We are able to quickly follow-up on patients who

have longer hospital stays than the "nominal". Each physician DRG utilization is reviewed (by the medical staff leadership and administration) to see if patients are being treated in a cost effective manner. Having the data in a readily available computer form allows the medical staff leadership to review the performance of their colleagues and allow for exceptions based on extenuating circumstances or take corrective action where necessary.

7. Please explain in more detail how "electronic signatures" are handled by the HELP System.

Nurses currently use an "electronic signature" to sign off nursing notes in our intensive care units. Each nurse is given a unique code which allows them to verify information on their patients. The code and time are stored in the patient record. On "shifts" where multiple nurses care for a patient the final nurse also initials the computer generated patient record with his/her name. If changes in the record are required at a later time only the supervising nurse is authorized to make the changes.

8. Has the HELP system ever failed to alert the hospital staff to problems in a patient's condition, even though the information was available in its knowledge base?

I am sure the system has failed to alert the staff to "alert" conditions. However, I can't remember such a failure when the system was "running" and when the programs used were fully validated. Most of this type failure occur during the development and validation phases of projects. We work very hard at minimizing system "bugs" and other problems which could lead to this type failure. It should be remembered that the computer system is primarily a back-up for physicians and thus physicians still hold primary responsibility for the care of the patient (the physicians are the "captains of the ship"). The HELP system is an information generator and does not "close the loop" (such as injecting a drug) in any of the decision feedback. Not all of medical knowledge and not every contraindication known to man are coded into the HELP computer system.

9. How has the HELP system used in the performance of medical research?

The HELP system with its extensive data base provides a rich resource for answering medical and administrative questions. The structure and organization required by a computer data entry have

dramatically improved our capability to collect reliable data. We can make queries of the data base to test scientific hypothesis. We also test new decision-making strategies by applying them to the "retrospective" data base thus helping us to check and validate new concepts more quickly. "Before and after" studies are usually very easily performed since the "before" data is already available in the patient records.

I have included prints of the slides used during the hearing. I too appreciate the opportunity of being able to present what I think is unique and effective computer system developed by a team of dedicated and talented computer and medical scientists. I am but only a small part of that team and want to extend to my professional colleagues the just due that they deserve.

Sincerely,

Reed M. Gardner

Reed M. Gardner, Ph.D.

Enclosures

Application Form

I am interested in having telephone access to the LDS Hospital Information System (HELP). I understand there is a $250.00 installation fee with service charge of $30.00 per month which will be billed quarterly. I presently have the following computer and communications equipment.

Personal Computer: (MS.DOS Compatible)	IBM PC ____	IBM PC XT ____
	IBM PC Jr ____	IBM PC AT ____
	Leading Edge ____	
	Zenith 150 ____	
	TRS 2000 ____	
	Other ____	Specify _____
Modem:	Hayes ____	Model _____
	Avatex ____	Model _____
	Signalman _____	Model _____
	US Robotics ____	Model _____
	Other _____	Model _____
Printer:	Epson ____	Model _____
	Other ____	Model _____

PATIENT PRIVACY

I agree to maintain the floppy disc I am provided in a secure place and will be responsible for any computer system access with the "logon security code" recorded on the disc. In addition I agree to maintain the patients privacy in the same way I would by having access to computer and other patient records just as if I were on site at LDS Hospital. I will notify the Biophysics Department at LDS Hospital if my floppy disc is lost or stolen so that my security code can be removed from the system.

HOLD HARMLESS AGREEMENT

I further agree to hold LDS Hospital harmless from any claim in tort, contract or other legal theory arising out of my use or use through my access code of the LDS Hospital Information System (HELP) or of any information derived through such use.

_____ Date

_____ Signature

Return Application to:
Reed M. Gardner, PhD
LDS Hospital
325 8th Avenue
Salt Lake City, Utah 84143

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUITE 2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, D.C. 20515

(202) 225-6371

21 May 1991

Mr. William Baker, Jr.
5601 Garden Lakes Majestic
Bradenton, Florida 34201

Dear Mr. Baker:

Enclosed is a copy of the transcript from the April 23, 1991, hearing at which you testified before the Subcommittee on Investigations and Oversight on information technologies in the health care system. Attached to the transcript are instructions for submitting requests for changes or clarifications. Please review these instructions and the enclosed transcript of your testimony carefully. Your copy of the transcript, together with any written requests for changes, should be returned by June 30, 1991, to:

James H. Fay
Subcommittee on Investigations and Oversight
B22 House Annex 1
Washington, DC 20515-6301

The Subcommittee has developed further questions as a result of the hearing, and would appreciate receiving your responses to them. You may include them with your transcript.

1. In your search for venture capital, how did you describe your company and the market you were pursuing?

   a. Please supply the Subcommittee with a copy of your prospectus for investors.

2. What steps have you taken to assist system developers with the problems you have identified?

   a. What progress has been made in preventing expert systems from exceeding their knowledge domain?

   b. How will knowledge bases be updated after these systems become widespread?

   c. Has your company provided funds for research in order to detail answers to these problems?

3. You stated during the hearing that venture capital could be found to handle the expense of validating these systems. Has any system designer accepted an offer of financial assistance from your company for this purpose?

Mr. William Baker, Jr.
20 May 1986
Page Two

4. How will you choose the scheme that will govern verification of the expert systems you will market?

5. In your opinion, does the enclosed statement, provided by FDA for the record, represent progress toward satisfying the concerns of computerized medical device manufacturers?

   a. FDA says in its statement that the field of computer applications in medicine is in such great ferment that they cannot identify a pattern to use in developing guidelines. Do you agree with that assessment?

   b. Do you believe that FDA's attempt to regulate this field will interfere with your efforts to market these information systems?

   c. How will you be able to market medical expert systems if, as you recommend, FDA exerts the development of its own in-house expertise before it proceeds to establish a regulatory structure?

6. FDA defines a Class I medical device as "...laboratory equipment whose uses are generally known by persons trained in this area and which are not labeled or promoted for general uses." Can CADUCEUS meet that standard?

   a. For a Class 2 device, FDA requires the establishment of a performance standard. How would you set such a standard for CADUCEUS?

   b. Have you ever considered offering any of these expert systems to non-specialists, or do-it-themselves?

7. Enclosed is a copy of a statement submitted for the record by the National Institutes of Health.

   a. Are you satisfied with the current focus of NIH research in the application of artificial intelligence techniques to medicine?

   b. What changes or new areas of emphasis would you recommend?

Mr. William Baker, Jr.
20 May 198X
Page Three

Your testimony at the hearing was extremely valuable to the members, and I want to extend our thanks for your participation and service to the Subcommittee.

Sincerely,

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

June 24, 1986

Knowledge Research Associates
5601 Garden Lakes Majestic
Bradenton, FL 34023

(813) 755-6262

James H. Paul
Subcommittee on Investigation
and Oversight
Committee of Science and Technology
U.S. House of Representatives
822 House Annex I
Washington, DC 20515-6307

Dear Mr Paul:

Thank you for the opportunity to follow-up on the April 21, 1986 hearing. The move to Florida has stolen more time than I had planned. My business has maintained contacts but has made no substantive progress since April.

In addressing the questions you have asked I have had some concern about disclosure of proprietary information contained in our draft business plans. I would appreciate your limiting circulation to those individuals who need to know in conducting the business of the House.

Question 1.
Answer 1. The vignette in Business Week July 9, 1984 provided most of the description needed by the venture capital organizations. Market definition is at present limited to physician customer/users. The family and general practitioners constitute the largest market segment.

Answer 1.a A draft business plan is attached. The plan is dated and does not reflect the current state but I believe it gives adequate insight to our plans.

Question 2.
Answer 2. Our relationship with system developers has been almost solely limited to advice on management and techniques to protect their intellectual rights.

Answer 2.a The system developers have yet to build self recognition of problems outside the knowledge domain of their systems. They believe, along with us, that until the technology for doing this is developed and tested, written instructions on the limits of domain expertise must preface initial use and use after each knowledge base up-grade.

Answer 2.b

Knowledge-base updates will be handled by:

Independent review of new knowledge,

Independent recommendation of update action,

Independent determination of the ripple effect of new knowledge on the system,

Corporate action updating customer systems subscribing to this service, and

Notification to non-subscribers that the update exists and the gist of its clinical substance.

Since we believe that the systems will sold on a turnkey basis, the above updating will be handled remotely without user intervention.

Answer 2.c

My organization has no funding for the basic problem of recognizing knowledge domain boundaries. This is a fundamental computer science problem with a concomitant high risk beyond the scope of our company.

Our company has no intention of marketing a product without financing a committed base for the product representing a national consensus and a mechanism for knowledge base updating over the life of the product.

Answer 3

No system developer has accepted our offer to begin validation supported by our funds.

Answer 4.

The schema for validation (verification) will be a process where domain specialists selected by users in that domain and supported by corporate set aside will examine contemporaneous literature for new knowledge, validate that which is significant to the domain, and recommend to the company appropriate updates with notification of the effects of the new knowledge on system operation.

Answer 5. It had not occured to me before responding to this question that the FDA might have a role in the future of artificial intelligence expert systems. It may satisfy industry concerns if the FDA was the administrative home of the clinical domain specialist units organized to develop national concurance and produce update recommendations when and where appropiate. This would go a long way in eliminating public concerns with corporate support of such activities.

Answer 5.a I agree with the notion that the computer field in medicine is changing very rapidly making the job for developers, watchers, and regulators extremely difficult. The FDA should develop a formal program to work with emerging clinical applications which may or may not go to commercial diffusion.

Answer 5.b I believe that with the present attitudes in place at the FDA, any attempts to regulate would close my opprtunities for marketing clinical expert systems.

Answer 5.c I believe if FDA follows closely the development of national consensus in each of the clinical applications its notion of regulating usage will be the same as it holds in licensing of physicians by the states, is no role.

Answer 6. I cannot answer this question for I do not know what is meant by "general uses". If it means "over the counter," I agree. If it means in general use by physicians or trained physician augmenters, I do not agree.

Answer 6.a In setting a performance standard for CADUCEUS, I believe a process similar to the NIH's consensus development should be used regardless of the class of the clinical expert system.

Answer 7 Some time before I left the NIH I felt that this method of representing knowledge could be extended down to the triage system. I still believe this to be true. Personnel trained to augment the functions of a physician could also become qualifed users of these systems.

I believe it will be decades before these systems can be successfully used in the over-the-counter mode.

Answer 8.a

The dual programmatic thrust at the NIH is interesting in that the National Library of Medicine (NLM) is making substantive contributions to the field and is actively promoting the field while the Division of Research Resources (DRR) leadership seems to have difficulty supporting aritficial intelligence in medicine and insists on maintaining a caretaker role. (I have several ancedotes substantuating this style of program management.) I am not satisfied that.there is adequate competency or knowledge among the top management and program staff of the DRR to determine future directions, long range goals, or programs to attain those goals in clinical systems. The research resources and projects initiated and supported by the DRR during the 1970's and early 1980's are not currently attracting new investigators and new ideas to these DRR activities. It does not inspire my confidence that our funds in this area are best handled by the DRR.

On the other hand as DRR's capabilities have fallen, the NLM has performed admirably in recent years. The NLM hosted the most recent annual workshop conducted by the community of artificial intelligence in medicine, has vigorous and,.broad programs that are bringing new results into the field, and, as a further plus, has its own built-in research activity in the Lister Hill Center.

Answer 8.b

I recommend the funds and programmatic mission (research resources) of the DRR in artificial intelligence in medicine be transferred to the NLM. The NLM now serves as the nation's focus within the executive branch for these activities and by its very nature is epistemological. Therefore the NLM can provide an administrative and philosophical home for the field of knowledge-based expert systems within the NIH. It now has the leadership and constituency to deal effectively with the future of expert clinical systems.

I hope this is responsive to your needs. If more or changes are needed please don't hesitate to let me know.

Sincerely yours,

Bill Baker

William Roy Baker, Jr.

[illegible]

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUITE 2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-6371

[illegible]

21 May 1986

Professor Vincent Brannigan
Department of Textiles and Consumer Law
University of Maryland
2100 Marie Mount Hall
College Park, Maryland 20742

Dear Professor Brannigan:

Enclosed is a copy of the transcript from the April 21, 1986, hearing at which you testified before the Subcommittee on Investigations and Oversight on information technologies in the health care system. Attached to the transcript are instructions for submitting requests for changes or clarifications. Please review these instructions and the enclosed transcript of your remarks carefully. Your copy of the transcript, together with any written requests for changes, should be returned by June 30, 1986, to:

James H. Paul
Subcommittee on Investigations and Oversight
822 House Annex I
Washington, DC 20515-6301

The Subcommittee has developed more questions as a result of the hearing and would appreciate your response. You may submit these at the same time you return your transcript.

1. Assuming your regulatory scheme is adopted, what would be the effect on a medical information system like the HELP system?

2. Because software is often customized for the hardware that supports it, can hardware manufacturers expect to be included in liability actions as a result of the use of these systems?

   a. Would you read the FDA policy on stand-alone software to imply that computer hardware manufacturers would be required to submit their products for FDA review on the chance that they might one day be used with medical software?

3. In the testimony you have submitted for the record, you indicate that the greatest threat computerization poses to patient privacy is remote access capability.

   a. How would you evaluate the position Dr. Gardner and Dr. McDonald expressed on data security and the necessity of access?

Professor Vincent Brannigan
21 May 1986
Page Two

4. What criteria have the courts applied to determine when medical technology has become the "standard of care" for the purpose of evaluating treatment?

a. How has this affected malpractice law?

In order to assure a complete record for this hearing, please submit the 1983 article from the Journal of Consumer Policy and the article by Bruce Watson you discussed at the hearing. Also, please annotate your remarks on Justice Holmes' opinion (p. 116) with the appropriate citation.

Your testimony at the hearing was extremely valuable to the Members, and I want to extend our thanks for your participation and service to the Subcommittee.

Sincerely,

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

THE UNIVERSITY OF MARYLAND

COLLEGE PARK CAMPUS
Department of Textiles and Consumer Economics

September 18, 1986

Mr. James Paul
Subcommittee on Investigations and Oversight
822 House Annex 1
Washington, DC 20515-6307

Dear Mr. Paul:

In answer to your inquiry:

1. I believe that all users of Medical information systems should be registered in a central location, with a reasonable amount of information on how the system is used.

2. Hardware liability problems are remote, with the possible exception of direct hardware problems, such as system crashes due to hardware defects. False promotion of reliability or compatibility may be an additional problem.

2a. No, I do not think the hardware manufacturers would be covered.

3. Without reference to Drs. McDonald or Gardner on a personal basis, I am convinced that many medical informatics professionals seriously underestimate the need for security of patient data, and the ease with which such data is removed from systems.

4. This question is difficult to answer without examining the entire field of medical malpractice and computer law. I have enclosed a copy of "Liability for Failure to Acquire or Use Computers" by Bruce Watson, which covers this area.

Thank you for the opportunity to testify.

Sincerely,

Vincent M. Brannigan
Associate Professor

VMB/mc

College of Human Ecology
2100 Marie Mount Hall
College Park, Maryland 20742 (301) 454-2141

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUITE 2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-6371

20 May 1986

Dr. Clement McDonald
Director, Medical Information Sciences
Regenstreif Institute, 5th Floor
1001 W. 10th
Indianapolis, Indiana 46202

Dear Dr. McDonald:

Enclosed is a copy of the transcript from the April 21, 1986, hearing at which you testified before the Subcommittee on Investigations and Oversight on information technologies in the health care system. Attached to the transcript are instructions for submitting requests for changes or clarifications. Please review these instructions and the enclosed transcript or your remarks carefully. Your copy of the transcript, together with any written requests for changes, should be returned by June 30, 1986, to:

James H. Pau
Subcommittee on Investigations and Oversight
822 House Annex
Washington, DC 20515-6301

The Subcommittee has developed further questions as a result of the hearing and would appreciate your response. These may be submitted at the same time you return your transcript.

1. Where will expert systems make their greatest contribution to medical care?

2. You note in your testimony that our understanding of physician decisionmaking is weak. Will a better understanding of that process come from research into expert systems, or should separate research be done in this area?

   a. Should expert systems be used to critique physician decisionmaking?

3. How does the regulatory philosophy embodied in the FDA statement "impose...an overburden of rules and regulations?"

   a. Why do you believe this will deter research in this field?

   b. One of the criteria an FDA advisory panel will consider is the reliability of the "device." Do you agree with the statement, "in general it is impractical to test [software] for every... opportunity for failure. The best that can be achieved is a finding that the state-of-the-art of testing such devices has been applied and acceptable results obtained."

Dr. Clement McDonald
20 May 1982
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3. c. Does this mean that until the problem of verification is solved, no progress can be expected in establishing regulatory guidelines in this field?

4. Would Professor Brennigan's idea to place the regulatory burden on the software user be an acceptable substitute?

a. What problems would you foresee with Professor Brennigan's approach?

5. Enclosed is a copy of the statement submitted for the record by the National Institutes of Health.

a. Are you satisfied with the current focus of NIH research in the application of artificial intelligence techniques to medicine?

b. What changes or new areas of emphasis would you recommend?

Your testimony at the hearing was extremely valuable to the Members, and I want to extend our thanks for your participation and service to the Subcommittee.

Sincerely,

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

INDIANA UNIVERSITY

SCHOOL OF MEDICINE

DEPARTMENT OF MEDICINE
Regenstrief Health Center, 5th Floor
1100 West Michigan Street
Indianapolis, Indiana 46223
(317) 630-6374

Reply to:
Wishard Memorial Hospital
1001 West Tenth Street
Indianapolis, Indiana 46202

July 3, 1986

Mr. James H. Paul
Subcommittee on Investigations and Oversight
822 House Annex I
Washington, DC 20515-6387

Dear Mr. Paul:

In the following, I attempt to answer the additional questions developed by the subcommittee.

1. Where will expert systems make their greatest contribution to medical care?

I think the emphasis in this question is misplaced. Expert systems are only one part of a larger whole including medical record systems, database storage techniques, human interfaces, display techniques, and all statistical analysis techniques--all of which are components of clinical information systems. Asking where expert systems make their greatest contribution to medical care is somewhat similar to asking how headlights will make a contribution to personal transportation. The automobile makes the contribution to transportation, the headlights are only a part of that automobile.

If you let me answer the question, "Where will intelligent clinical systems make their greatest contribution?", I would say to the accuracy of diagnosis and management, and to the cost of clinical care. Ultimately, clinical systems will make care faster--requiring less personnel and physician time. They will greatly rationlize the entire field of care as well. Closed-loop systems will have marvelous effects ranging from automated defibrillation in patients with ventricular instability to automatic insulin delivery in diabetics with embedded insulin reservoirs.

2. You note in your testimony that our understanding of physician decisionmaking is weak. Will a better understanding of that process come from research into expert systems, or should separate research be done in this area?

Research in expert systems does contribute to the understanding of the decision process, but direct study of the process itself is a more efficient way to learn about it. Psychologic studies and work such as that performed by Elstein from the University of Illinois needs greater support. Support is particularly important now that computer techniques have evolved to the point where they can imitate what we "think" the physician does. Given this power to imitate, it is all the more important that we understand what the physician is really doing.

2.a. Should expert systems be used to critique physician decisionmaking?

Important work has been done in the area of expert-system critiquing by Dr. Perry from Yale University. It is one of the many interesting pathways being explored. The field is too young to be talking about what should be done, however.

3.a. How do you believe this [the regulatory philospohy embodied in the FDA statement] will deter research in this field?

I did not receive a copy of the FDA statement presented at the subcommittee meeting of April 21, 1986, so I can't comment on the substance of that particular statement, but the general problem with regulation is that it is easy to come up with rules, but difficult to come up with regulations, especially regulations that are appropriate. When the regulators aren't practitioners in either the field of medicine or computer science, and they are to regulate the applications of computer science techniques to the practice of medicine, the odds that the regulations will match the realities are low. And when the field being regulated is so embryonic that there are very few examples of what the field is, the likelihood of mismatch increases. Regulations, by definition, impose strictures on how systems are developed, tested, and/or distributed. This generally imposes burdens of paperwork and hearings or other such time consuming efforts on investigators. The cost of "jumping" the regulatory barriers will tend to exclude the smaller and more inventive companies from involvement in the field because they have neither the personnel, the time, nor the capital to endure regulation delays. It will usually deter researchers from entering the field because their research energies will be tethered.

3.b. Do you agree with the statement, "In general it is impractical to test [software] for every ... opportunity for failure."

I agree with the statement because it is absolute fact. The problem is compounded by the need to change software. Changes are required to accommodate new hardware, new medical realities, new algorithmic approaches, and so on. In contrast to a drug, which remains the same during its patented lifetime, software must change to keep up with other realities. The need to pass software through the regulatory hurdles after every modification could impose hopeless costs and delays in the software development cycle.

3.c. Does this mean that until the problem of verification is solved, no progress can be expected in establishing regulatory guidelines in this field?

Yes, but I keep coming back to the question of what problem are we trying to solve with regulation? What excess has occurred? What excess is expected? What are the bad experiences the medical field has had with intelligent computer systems over the last twenty years that need to be corrected? Regulation for its own sake is bureaucratic excess in its purest form.

4. Would Professor Brannigan's idea to place the regulatory burden on the software user be an acceptable substitute?

I didn't fully understand the legal discussion between Mr. Brannigan and the subcommittee, but the idea of letting medical institutions decide what software is best for them is appealing. They already have substantial incentives, in the form of malpractice and liability issues, to choose only safe and useful software. I fully agree with Mr. Brannigan's arguments that medical software is not a device and therefore doesn't fall under that FDA's jurisdiction. I am not sophisticated enough in matters of law to give insightful criticism as to the possible legal problems with Mr. Brannigan's approach.

5. Are you satisfied with the current focus of NIH research in the application of artificial intelligence techniques to medicine?

This question requires an answer similar to that given for Question 1. Artificial intelligence techniques are only one of many techniques needed to produce useful clinical systems, and I don't think it is appropriate to single out one particular technique for individual support. Asking the broader question,

"Has NIH provided sufficient support for the research and development of clinical computing systems?", I would have to say no. Support has been provided by the National Library of Medicine, DRR, and the National Center for Health Services Research (not within NIH). The latter has provided the most support for research and development in clinical computing over the last 15 years, but their funding has been sharply reduced to one-fourth of the 1970's level. The problem with current support by NIH is that it's fragmented, and in many cases the "research" side of the research and development question has been underemphasized, particularly when work has been funded by one of the disease-based institutes. The National Library of Medicine is a reasonable agency on which to focus more of the support for clinical computing. However, a pure focus on artificial intelligence or expert system techniques is wrong. Research across a broad series of fronts, including means for storing patient data, efficient access techniques to large databases, integration of medical knowledge (textbook information) and patient facts (medical record), research and user interface, better understanding of the physician decision process, and rapid statistical techniques for dealing with irregular data sets, are all necessary for substantial advances to be made in this field. A pure focus on artificial intelligence would be analogous to focusing on only jet engines when trying to developing a jet airplane. Simultaneous work on airframe development, aerodynamics, environmental control, communication, and so on, are all necessary to build a successful airplane. The same will be true of clinical information systems. An amalgam of different technologies is going to be necessary, and more quantitative approaches should be taken.

With best regards,

Clem McDonald

Clem McDonald, M.D.

Professor of Medicine and
Director of Medical Information Sciences
Regenstrief Institute

CJM/jlm